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Applying Conversation Analysis to Family Therapy Process Research

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Contents

Thesis Abstract

This manuscript explores the application of Conversation Analysis, an empirical approach to the study of naturally occurring everyday interactions, to the field of family therapy process research. Conversation Analysis is claimed to have the potential to benefit family therapy process research by providing evidence of effective therapist-family interactions and producing evidence of in-session change. However, these claims have rarely been substantiated by references to occasions in which this has been the case. This manuscript aims to address these claims in two ways: firstly by reviewing all the literature on family therapy process research that has adopted Conversation Analysis as a methodology of choice; secondly by providing an example of how Conversation Analysis can be used to explore the interactional consequences of a specific therapeutic strategy, psychoeducation, within the context of a feasibility study for a novel family therapy intervention. Finally, this manuscript provides a reflection on future research directions, theoretical developments and the clinical implications of using this methodology, thus providing a comprehensive picture of the application of Conversation Analysis in the field of family therapy process research as well as some evidence of its potential practical utility.

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LITERATURE REVIEW

Has Conversation Analysis Delivered for Family Therapy?

Has Conversation Analysis Delivered for Family Therapy?

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FAMILY PROCESS

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Abstract

Conversation analysis (CA) is often presented as an ideal research methodology for family therapy process research. The aim of this systematic literature review is to investigate how researchers studying family therapy use CA methodology, what type of findings the use of this methodology has led to, and what contributions have been made to the field of family therapy as a result. Findings from twenty-one papers investigating conversational practices used in family therapy have been examined, summarised and drawn together. As a result two macro-processes of family therapy have been mapped: an *Alliance Building Process* and an *Outcome Pursuing Process.* Limitations and directions for future research are discussed.

Introduction

Family therapy has consistently defined itself as a paradigm distinct from individual psychotherapy (Hoffman, 1981). Its unique nature derives from its origin in general systems theory (Bateson, 1972). Systems or systemic theory suggests that each person's action is influenced by others and influences others simultaneously. Any action is therefore also a response, and a response is also an action. This notion of interdependence of behaviour gave rise to the concept of circular causality, which has presented a challenge to traditional quantitative research (see Appendix 1). Additionally, Bateson proposed that all communications are accompanied by metacommunications that colour what is being communicated (1972). Early schools of family therapy made use of this notion to explore how metacommunications may contradict or disqualify the content of communications creating confusion in the mind of the recipient (Dallos & Draper, 2010). CA has been identified by many authors as an ideal methodology to research family therapy process as it is both sensitive to systemic epistemology and circular causality and, through its attention to paralinguistic features of talk, provides a framework to study metacommunication as well as the content of communication (Gale, 1991; Strong, Busch & Couture, 2008).

CA is claimed to have the potential to fill two gaps in family therapy research(see Appendix 2). Firstly, it promises to aid theory development by describing the moment-by-moment exchange between therapist and family, thus highlighting effective therapeutic processes (Gale, 1991). Secondly, some have argued that CA can produce conversational evidence of moment-by-moment change, thus demonstrating the effectiveness of family therapy (Strong et al., 2008a). Nonetheless, these claims are rarely substantiated by references to occasions in which this has been the case. The aim of this review is to investigate these claims by reviewing how researchers studying family therapy use CA methodology and what type of findings have resulted from the use of this methodology.

Conversation Analysis and Discursive Psychology

Conversation analysis was developed as an empirical approach to study how social action is achieved in naturally occurring everyday interactions (Sacks, Shegloff & Jefferson, 1974). The aim of CA is to describe and explore the competencies that ordinary speakers rely on when participating in interaction (Heritage, 1988), uncover the regularities of speech production and record how exceptions to these regularities are exploited in order to achieve particular actions (Antaki, 2008).

Unlike other language-based approaches (see Appendix 3), CA explains how participants' way of talking shows that they have understood each other, without the need for analyst interpretation (Schegloff, 1997). It does so by exploring in detail through a sophisticated transcription style (Jefferson, 1985) all aspects of interaction, even those that seem accidental, irrelevant or ungrammatical (e.g. pauses, restarts, etc.). CA only accepts what is actually said and how it is said in the context of what was said before as evidence for its claims (Madill, 2015).

CA follows a detailed process of evidence gathering. Initially, a phenomenon of interest can be identified though the minute examination of one case. Subsequently, a collection of instances of the candidate phenomenon is gathered and cross-comparison of these instances is used to determine whether they share common properties. A sequential account of the phenomenon of interest is then developed, which involves close inspection and examination of the sequences that precede or follow the candidate feature. Finally, if other instances of the phenomenon can also be described by this account, the analyst can claim the individuation of a conversational practice by presenting a carefully evidenced and argued case using detailed analysis of examples of real conversational data (Wooffitt, 2005; Madill, 2015). Reliability and validity are therefore achieved through prolonged engagement with the

data, persistent observation, deviant case analysis, constant comparative analysis and use of detailed transcription which allows other researchers to re-analyse the extracts presented (Gale & Newfield, 1992).

The body of knowledge built through this process has been exploited by other language-based approaches. However, one approach in particular has provided a fruitful collaboration with CA: Discursive Psychology (DP; Wooffitt, 2005; Antaki, 2008). DP was developed from Discourse Analysis as a critique of traditional psychology research. DP aims at revealing how psychological terms are used rhetorically to achieve goals in interaction and construct specific versions of events (Edwards & Potter, 1992). DP uses CA methodology to make interpretations about the agendas behind the use of certain rhetorical tools by participants in the interaction (Wooffitt, 2005). It has been argued that there is no clear cut distinction between CA and DP especially in psychotherapy interaction research where both social action and the use of psychological terms are of key importance (Wooffitt, 2005). For these reasons, the decision was made to include in this review both papers that claimed to use CA and those that claimed to use DP. Interestingly, all papers claiming to use DP to study family therapy also referred to CA literature.

Methodology

A systematic approach was taken to identify studies of family therapy that used CA as a method of data analysis. The search terms mirrored Tseliou's methodological review (2013). In her review Tseliou addressed methodological and research quality issues only and did not explore the findings of individual studies. This review which will instead focus on the content of the findings of CA papers.

PsycINFO, PubMed and Web of Science databases were searched for papers containing the following terms in their main body: "conversation analysis" OR "discursive

psychology" AND ("family therapy" OR "systemic therapy" OR "systemic family therapy") from 1970 onwards. In parallel, the same search criteria were applied to three leading journals in the field (*Family Process, Journal of Family Therapy,* and *Journal of Marital and Family Therapy*). Studies using CA to analyse family therapy supervision or to develop innovative training methods were not included (Ratliff, Wampler & Morris, 2000; Pendry, 2012; Lawless, Gale & Bacigalupe, 2001). Only papers published in English language, in peer-reviewed journals were considered (*n*=45).

The following inclusion criteria were devised based on the characteristics of CA mentioned above. Because of CA's focus on naturally occurring data (Sacks et al., 1974) only papers that used family therapy sessions as data were included, whilst papers using data from conference interviews or interviews with actors were not (Harvie, 2008; Hutchby & O'Reilly, 2010; Kogan, 1998; Kogan & Gale, 1997). Also excluded were papers that used extracts from other CA studies to make theoretical claims (Strong & Sutherland, 2007; Strong et al., 2008a). Papers claiming to use CA were included whilst papers referring to CA as an inspiration but presenting an idiosyncratic methodology were excluded (Roy-Chowdhury, 2006; Sutherland, Turner & Dienhart, 2013; Kurri & Wahlström, 2005; Muntigl, 2004; Suoninen & Wahlström, 2009; Mudry et al., 2016; Guillefoyle, 2002). Also omitted were papers that mentioned analysing conversation but did not quote CA or its founding authors: Sacks, Schegloff and Jefferson (Stamp, 1991). Papers that appeared to be using CA, but did not claim to do so were also excluded (Stancombe & White, 1997; 2005). Two key features of CA are the presentation of extracts of the data under analysis and the use of detailed transcriptions. For this reason papers that used CA in a wider study but reported data from a different analysis were excluded (Charles, 2012; Friedlander, Heatherington & Marrs, 2000), as were papers presenting extracts in orthographic transcription (Diorniou & Tseliou, 2014; Patrika & Tseliou, 2015; Rober, Van Eesbeek & Elliott, 2006). Other papers were excluded

as the authors presented data that was later re-analysed and better developed in following papers (Couture & Strong, 2004; Strong, Couture, Godard & Hope 2008; Sutherland & Couture, 2007). Twenty-one papers meeting this criteria were identified, only seven of which were included in Tseliou's review (2013).

Literature Identified

All papers included presented English language data. The data originated from videotapes of family therapy sessions in child and adolescent mental health settings, with the exception of two papers on couples systemic therapy (Gale & Newfield, 1992; Sutherland & Strong, 2011) and one of family therapy in an adult learning disability service (Pote, Mazon, Clegg & King, 2011). The aims of the papers vary between how aspects of family therapy technique are performed, how topics are addressed and managed during the session, how alliance is managed within the family therapy setting, how the therapist pursues and obtains a particular outcome and how aspects of talk (e.g. word selections, paralinguistic features, etc.) are used in therapy (see Table 1 for summary).

Table 1. Summary of literature identified.

Authors	Data	Research Question	Methodology
Couture, 2006	One session with Karl Tomm.	How do therapists and family members move beyond impasses in therapy?	CA of passages identified by family as evidence of "forward moving conversation".
Couture, 2007	One session with Karl Tomm.	How do the therapist and family members engage multiple conversational partners?	CA of passages identified by family as evidence of "forward moving conversation".
Couture & Sutherland, 2006	One session with Karl Tomm.	How does a collaborative therapist offer advice?	CA of passages identified by family as evidence of "forward moving conversation".
Gale & Newfield, 1992	One session with Bill O'Hanlon.	How does an expert therapist use language to achieve particular therapeutic outcomes?	CA used to identify and categorize of patterns of interaction.
Muntigl & Horvath, 2016	First 10 minutes of session with Salvador Minuchin.	How does an expert therapist build alliances and repair ruptured alliances?	CA of excerpt selected by Minuchin as demonstration of his method.

O'Reilly, 2005a	22 sessions – four families, two therapists.	How do families report their dissatisfaction with professional bodies?	DP and CA of excerpts that were of most interest in relation to research question.
O'Reilly, 2005b	22 sessions – four families, two therapists.	How are abstract noises and onomatopoeic terms used in family therapy?	CA of excerpts with abstract noises and onomatopoeic terms.
O'Reilly, 2006	22 sessions – four families, two therapists.	How are children's interruptions treated in family therapy?	Use of CA definition of interruption to select excerpts, followed by CA of responses to interruptions.
O'Reilly 2007	22 sessions – four families, two therapists.	Which social actions are accomplished by parents' use of the term 'naughty'?	DP and CA of excerpts including the word 'naughty'.
O'Reilly, 2008	22 sessions – four families, two therapists.	How do parents talk about punishment as a way of managing their children's challenging behaviours?	DP and CA of excerpts that referred to punishment.
O'Reilly 2014	22 sessions – four families, two therapists.	How do parents manage negative accounts of themselves and their family?	DP and CA of instances of blaming to identify what action it accomplished in the interaction.

O'Reilly 2015	22 sessions – four families, two therapists.	How do families construct their reasons for attending, their problems, their goals and progress in therapy?	DP and CA of excerpts in which reference was made to reasons for attendance, purpose of therapy and progression and outcomes
O'Reilly and Lester, 2015	22 sessions – four families, two therapists.	How do parents construct themselves as "good parents"?	DP and CA of excerpts in which parents use rhetorical devices to place themselves in a positive light.
O'Reilly & Parker, 2013	22 sessions – four families, two therapists.	How do children display engagement/ disengagement and how do therapists respond?	DP and CA of excerpts pertaining to the research question.
O'Reilly and Parker, 2014	22 sessions – four families, two therapists.	How do families talk about what is deemed inappropriate for their children and how does the therapist manage this?	DP and CA of excerpts pertaining to the research question.
Parker & O'Reilly, 2012	22 sessions – four families, two therapists.	How do therapists resist aligning with one family member and maintain therapeutic alliance with wider family unit?	DP and CA of excerpts pertaining to the research question.

Parker & O'Reilly, 2013	22 sessions – four families, two therapists.	How does the therapist manage the process of consulting with a reflecting team?	DP and CA of excerpts pertaining to the research question.
Pote, Mazon, Clegg & King, 2011	Four sessions – three families, two therapists.	How are issues of vulnerability and protection of adults with a learning disability discussed?	Thematic analysis to identify fragments of data where vulnerability and protection were discussed. CA analysis of excerpts identified.
Sutherland, 2005	One session and one transcript – two families, two therapists.	How is the therapeutic relationship performed by the therapist and family members?	CA of two excerpts: one from the author's data and one from Gale (1991).
Sutherland & Strong, 2011	One session with Karl Tomm.	How does the therapist negotiate a non-expert position while attempting to influence the clients?	CA of passages identified as collaborative based on previous literature.
Williams & Auburn, 2015	Five sessions – five families, three therapists.	How are polyvocality and paired talk performed by the therapists in the reflecting team ?	Paired talk was identified as a topic raised by the family in the session being redressed by the reflecting team. CA of excerpts identified.

Methodological Quality

A brief overview of the quality of the papers identified is presented here. While it is debatable whether qualitative research should be subjected to strict quality protocols similar to quantitative research there is a general agreement amongst researchers that clarity of purpose, methodological congruence and procedural precision are key to first-rate qualitative research (Atkinson & Delamont, 2006; Morse, 2015).

Although the papers identified presented clear aims and methodologies due to the stringent inclusion criteria they had to fulfil, they differed with regards to procedural precision such as: the explanation of how videotapes were selected, how transcription was approached, and how excerpts were identified for analysis and analysed. Some papers explained these procedures comprehensively (O'Reilly, 2005; 2008; 2012; 2014; Williams & Auburn, 2015). Others relied on referring to their methodological approach (O'Reilly, 2006; Parker & O'Reilly, 2012; O'Reilly & Lester, 2015). Occasionally, papers appeared theory driven rather than data driven, with an approach to finding extracts that proved the proposed theory, which is methodologically incongruent with CA (Muntigl & Horvath, 2016; Sutherland, 2005). Another paper claimed to have looked at therapists' repair of ruptures in the therapeutic relationship but presented no excerpts demonstrating this (O'Reilly & Parker, 2013). This reflects findings from Tseliou's methodological review (2013) which suggest that CA and Discourse Analysis literature in family therapy presents several "methodological shortcomings" (pg 667).

Findings

All papers were read and claims regarding findings were collected. These were analysed using a constant comparative methodology[1] to identify conversational practices that performed similar social actions (e.g. child engagement). Actions that appeared connected were linked to form processes (e.g. child disengagement practices – therapist child engagement practices – child reactions to therapist response). What emerged from this analysis were two "macro-processes". These were named *alliance building process* (Figure 1) and *outcome pursuing process* (Figure 2). Both processes are outlined below and the individual practices that contribute to the process will be presented in tables (see Tables 2 and 3). These will be grouped by their possible *therapeutic function*, meaning their contribution to the overall objectives of family therapy and potential *local consequence*, meaning the effect on the immediate context (Peräkylä, Antaki, Vehviläinen & Leudar, 2008).

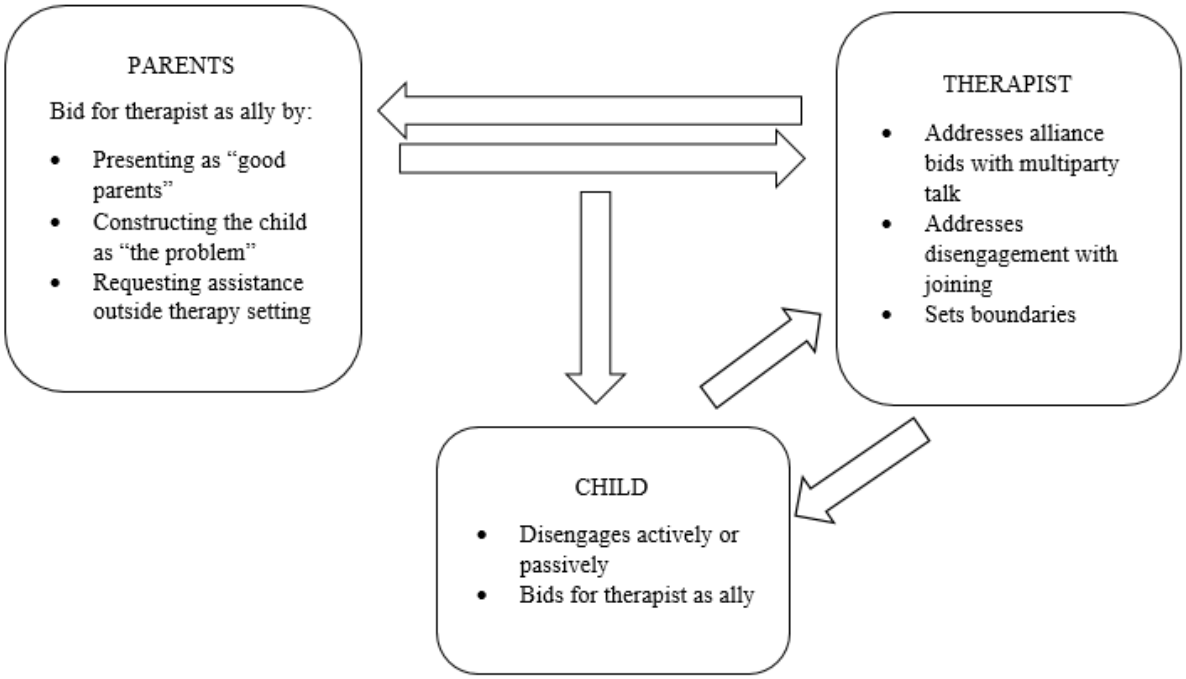
Alliance Building Process

This process regards the negotiation of the relationship between parents[2], identified patient[3], other family members and therapists (Figure 1). It is likely to be more relevant in the early stages of therapy and consists of the following micro-processes. The parents establish their identity as "good parents" in a bid to gain the therapist's alliance, convey the seriousness of their difficulties, pre-empt potential blaming and seek the therapist's advice. The therapist attempts to allay the parents' fears of being blamed by displaying a willingness to believe them and listen to their concerns, yet also places boundaries on the limits of the therapeutic role. As a result of this process the child can respond by passively accepting the parental narrative, disengaging from therapy or bidding for the therapist's alliance. In

[1] qualitative methodology which involves the comparison of instances of a phenomenon, in order to generate categories of that phenomenon and integrate those categories into a theory (Glaser, 1965).
[2] The term 'parents' will be used to identify the main carers of the identified patient.
[3] From here onwards the identified patient will be referred to as child.

response to or in order to pre-empt the child's reaction the therapist attempts to engage the child whilst simultaneously acknowledging the parents' perspective.

Figure 1. Alliance building process.



Several papers observe how parents, in family therapy sessions, use a variety of conversational practices to present themselves as "good parents" with a "difficult child". In accordance with CA epistemology there is no speculation as to why parents do this beyond a reflection that this behaviour might be in response to the context of being referred to *family* therapy, and therefore potentially either a practice to pre-empt being blamed for the child's behaviour or a way of presenting as responsible adults and therefore allies to the therapist. These parental practices create a dilemma for the therapist. The therapist needs to join the parents to ensure their engagement with the therapeutic process but doing so risks alienating the child leading to disengagement (see Table 2; Dallos & Draper, 2010).

Table 2. Summary of practices employed in the alliance building process.

1. Parent's actions		
Therapeutic function	**Local consequences**	**Practices**
-alliance building -child disengagement[4]	-child constructed as the problem -elicit therapist's acknowledgement -maintain positive self-image	Declaring to be a good parent acting in the child's best interest (O'Reilly & Lester, 2015)
		Complaining about outside agencies (O'Reilly & Parker, 2014)
		Referring to dealing appropriately with child's inappropriate behaviour (O'Reilly & Lester, 2015).
		Punishment described as restrained, necessary and mild, and contrasted with extreme nature of child's behaviour (O'Reilly, 2008)
		Reason for attending therapy is "fixing" the child (O'Reilly, 2014; 2015)
		Abstract noises and analogies used to create a vivid picture of uncontrollable behaviour of child (O'Reilly, 2005b)
		Child's accountability implied through use of the term "naughty" (O'Reilly, 2007)

[4] Child disengagement is to be seen as the function of the child's behaviour in the therapeutic setting.

		Reference to authoritative third parties (e.g. medical professionals), use lay mental health concepts or appeals to science to infer biological causation of child's behaviour (O'Reilly, 2014; O'Reilly & Lester, 2015).
		Evidencing practices: quoting what others have said about child, recruiting siblings as eye-witnesses, declaring honesty and truthfulness, providing physical evidence of harm caused by child, factual presentation of information (Parker & O'Reilly, 2012; O'Reilly, 2014)
-stray from therapeutic setting	-therapist states boundaries	Request practical assistance with third party agencies (O'Reilly & Parker, 2014)
2. Child's actions		
Therapeutic function	**Local consequences**	**Practices**
-disengagement	-solicits therapist's engagement strategies	Inattention, refusal to answer questions or ambivalent responses (e.g. "I don't know"), interruption via topic switches or use of noises (O'Reilly, 2006; O'Reilly & Parker, 2013)
		Resisting parental accounts (Parker & O'Reilly, 2012), expressing autonomy (e.g. I am not talking) and evading adult impositions (O'Reilly, 2006).
-engagement	-acknowledgement by therapist/family	topic relevant interruption(O'Reilly, 2006)

3. Therapist's actions		
Therapeutic function	**Local consequences**	**Practices**
-joining strategy	-parental engagement -child disengagement	offering praise (O'Reilly, 2014), positively reframing family as resilient (O'Reilly & Parker, 2013)
		stating explicit belief in parental account (Parker & O'Reilly, 2012)
	-child engagement	providing examples of what child might feel (O'Reilly & Parker, 2014)
		soliciting child's perspective (O'Reilly & O'Reilly, 2012)
		reflecting team emphasises child's point of view (Williams & Auburn, 2015)
	-family engagement	use of pronoun "we" (O'Reilly, 2014)
-change strategy	-shift focus to common goal of having a happy family and away from "fixing" the child	inviting family members into the conversation and soliciting multiple perspectives on the same problem (Pote et al., 2011, Couture, 2007), considering each perspective as an equally valid option to consider (Couture, 2006).
	-setting therapeutic space boundaries	Removing children from the room (O'Reilly & Lester, 2015), hinting at unhelpfulness of a topic, directly stating the limits of the therapist's role (O'Reilly, 2005a)

Outcome Pursuing Process

This macro-process regards the therapist's movement between different conversational practices according to family members' uptake or rejection of the therapist's previous statements (Figure 2). The therapist's conversational practices were noticed broadly to group into two categories: *change strategies* introduced a different way of viewing events or relationships (e.g. positive reframing, inviting another family member's perspective, reflecting team feedback); *joining strategies* conveyed an attendance to the family members' perspectives, an understanding of their experience and incorporation of their experience in the therapist's language (e.g. offering praise, seeking clarification, reformulating). Family members' responses to these conversational practices guided the therapist's choice of what to say next (see Table 3).

Figure 2. Outcome pursuing process.

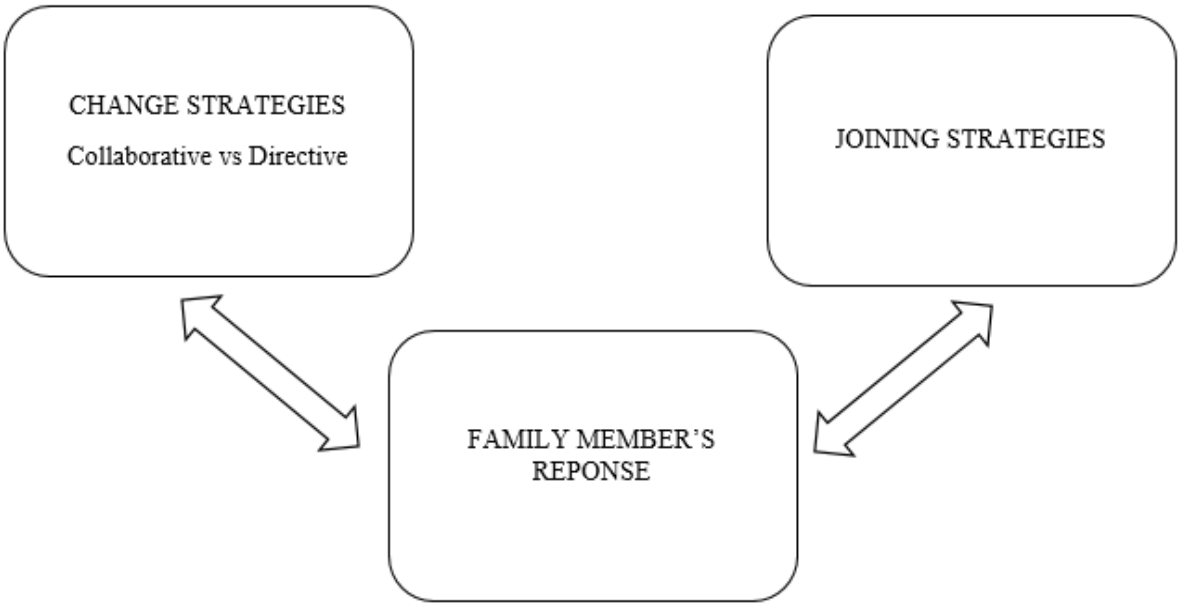


Table 3. Summary of practices employed in the outcome pursuing process.

1. Family member's actions		
Therapeutic function	**Local consequences**	**Practices**
-agreement with therapist	-therapist pursues with approach	Listener responses (e.g. "yes", "umhm") (Couture, 2006)
-partial agreement with therapist - disengagement	-therapist pursues -therapist reformulates to gain more solid uptake	Partial uptakes (e.g. "maybe", "I don't know") or reformulation of the therapist's formulation (Couture, 2006)
-avoid sensitive issue -request assistance	-therapist pursues or interrupts	Topic switch back to a negative view of the situation or invitation for other members to intensify the negative talk (Pote et al., 2011)
- disengagement	-therapist reformulates to gain more solid uptake	openly contest the therapist's assertions (Sutherland & Strong, 2011)
Note: all child disengagement strategies can be seen as a family member's responses to the family therapy process.		
2. Therapist's actions		
Therapeutic function	**Local consequences**	**Practices**

-change strategy	- interrupt negative narrative or complaint	Interruptions, anticipatory completion of a family member's sentence, the use of questions, humour and exaggeration to derail the family member from repeating a "problem" narrative (Couture, 2006; Gale & Newfield, 1992)
	-interrupting attempts to switch topic away from sensitive issues (Pote et al., 2011).	Ignoring partial uptakes or disagreements, treating an ambivalent response as legitimate (e.g. taking "I don't know" as meaning "I don't know") or pursuing with questioning until desired response is given (Gale & Newfield, 1992; Couture, 2006; 2007).
-collaborative practice	-maximise opportunity for interruption from family (Couture, 2006). -downgrading expert status	reformulating by including the family's expressed objections (Gale & Newfield, 1992), expressing doubt over formulation, explicitly inviting disagreement, using "pre-sequences" (e.g. "I'd like to ask you about...") (Couture & Sutherland, 2006; Couture, 2006; Sutherland & Strong, 2011), using hesitation markers, pauses, false starts, drawn out words, offering ideas as contestable (Sutherland & Strong, 2011; Couture, 2006), disguising advice as information (Sutherland & Strong, 2011), interrupting self when no signs of uptake from the family (Couture, 2006).

	-convey a formulation without ascribing it to the family	pairing strong language with vague descriptive categories and impersonal constructs as a way to convey a formulation without ascribing it to the family (Sutherland & Strong, 2011)
-directive practice	-push the therapist's agenda	Offering formulations by posing questions and answering them (Gale & Newfield, 1992), offering candidate answers to questions (Gale & Newfield, 1992, Sutherland & Strong, 2011), using authority to restructure family roles (Muntigl & Horvath, 2016) and positive reframing.
-joining strategies	-achieve joint understanding -display empathy	These strategies involve clarifying unclear references (Gale & Newfield, 1992), offering praise (O'Reilly, 2014), personal disclosure (Muntigl & Horvath, 2016), acknowledgement of the family's challenges (O'Reilly, 2014), attending to the reasons for child disengagement (O'Reilly & Parker, 2013), attending to partial uptakes (e.g. taking "I don't know" to mean "I don't agree") (Sutherland & Strong, 2011).
Note: the techniques described in Table 2 for managing the alliance building process could be included here.		

Change strategies can be performed either in a directive or a collaborative way. Directive approaches were common in studies of solution-focused family therapy and strategic family therapy (Gale & Newfield, 1992; Muntigl & Horvath, 2016), whilst collaborative therapists tended to perform the same type of strategies in a collaborative way (Couture, 2006; 2007; Couture & Sutherland, 2006; Sutherland & Strong, 2011). Collaborative performances of change strategies appeared to gain a more positive response from families whilst directive performances could lead to family members becoming entrenched in their position (Couture & Sutherland, 2006).

Discussion

Unlike other approaches to family therapy research, CA provides a way to explore the moment-by-moment use of language due to its attention to the detail and structure of interaction. It can shed light on how a theory-derived intervention is assembled and interpreted *in situ*, and allows for exploration of the interpersonal nature of therapy, in which both therapists and family members adapt to each others' communicative strategies in order to achieve a particular outcome.

Nonetheless, contributions of CA to the family therapy literature overall have been limited and unsystematic in their progress. Researchers have investigated separate practices without gaining much insight into how different practices relate to each other or to family therapy theory. Currently, CA literature in family therapy has mainly explored theory-relevant phenomena (e.g. collaborative practice, alliance building, etc.) rather than specific linguistic phenomena, and has yet to develop a corpus of knowledge. Additionally, although twenty-one papers were identified these papers were based on seven data-sets. More specifically, twelve papers were based on the analysis of one data-set all of which identifying different conversational practices within that data-set. Therefore, the findings are limited by

the context in which they arise. For example, findings regarding parental "positive self-presentation" come from family therapy sessions conducted in a clinic for children with neurodevelopmental disabilities. This context could be the driver of such parental presentation, and there has been no systematic attempt to look at how parents present themselves in other neurodevelopmental clinics or other family therapy settings. The literature therefore appears to re-state previously theorised concepts without discovering new actions or uncovering dissonances between theory and practice. The only exception to this is Gale and Newfield's work (1991) which uncovered previously untheorized practices in solution-focussed family therapy, and Parker and O'Reilly's (2013) work on strategies to consult the reflecting team that lead to better engagement outcomes.

CA is a sophisticated approach with its own language but so is family therapy. CA concepts cannot be inserted unchanged into gaps in therapy theory (Peräkylä et al., 2008). Throughout this literature attempts to insert unchecked CA or psychological terms that do not belong to the family therapy paradigm (e.g. "packaging talk", "validating"), as well as attempts to simplify CA transcription were noted. These practices can result both in family therapists being unable to use this literature and conversation analysts being unable to check the authors' claims. Both therapists and conversation analysts must learn each other's theories and languages in order to produce mutually useful and accountable research (Peräkylä et al., 2008).

The CA literature in family therapy so far provides snapshots of interactional practice. This review has attempted to pool those snapshots together into a larger scale map of the family therapy process. This type of cumulative approach of findings can hopefully allow for the collection of normative models of how professionals can interact with family members (Antaki, 2008), as well as highlight areas requiring further exploration (e.g. parental self-presentation in other settings) and provide practitioners with useful references should they

wish to explore specific conversational practices in greater depth. Furthermore, this type of review can highlight how universal therapy processes (e.g. alliance building) are negotiated in specific family therapy settings, in the awareness that this literature is not predictive but prospective: it offers possibilities of how interactions might unfold in a particular context.

One clear limitation of this review is the search methodology. Although great care was taken to ensure that only papers that actually used CA were included, this approach was potentially reductionist. The difficulty of untangling CA from other methods of analysis suggests that in spite of the limited literature identified, CA has inspired the development of a much broader, rich and varied literature that relies on the CA body of knowledge to explore family therapy processes.

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EMPIRICAL PAPER

Psychoeducation in Family Domains Therapy:

Therapist Strategies and Family Responses

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Abstract

Psychoeducation is a feature of Family Domains Therapy, an intervention based on Hill et al.'s work on family domains. Family psychoeducation has proven effective in improving outcomes for identified patients and their families, however it remains a controversial issue within contemporary family therapy, which encourages a "non-expert" therapeutic stance. This study is the first to use a Conversation Analysis informed methodology to explore the interactional impact of psychoeducation during therapy sessions. Findings suggest that in this setting psychoeducation was offered using four formats (non-technical scenarios, "if X then Y" format, technical paraphrase and formulation format). Families were more likely to give extended responses to non-technical scenarios. Therapists responded to minimal acknowledgements by resuming an assessment of the family's communication or by further explaining the therapy process. Implications for future research and clinical practice are discussed.

Introduction

Psychoeducation is the education offered to individuals about their mental health condition and optimal management strategies. Family Domains Therapy (FDT) is an approach that involves the provision of family psychoeducation regarding *family domains* and effective communication. This study explores the process of delivering and receiving psychoeducation in the context of a first session of FDT with families of young people receiving treatment for self-harming behaviour. To the authors' knowledge this is the first study to use a Conversation Analysis informed methodology in order to examine the interactional consequences of providing psychoeducation in a therapy session.

Family Psychoeducation

Family psychoeducation involves providing families with information about the identified patient's condition and treatment, common negative interaction cycles, and, where necessary, parenting techniques and assistance in developing more effective communication and problem-solving strategies (Lucksted et al., 2012). It includes cognitive, behavioural and supportive elements and shares characteristics with structural family therapy (McFarlane, 2016). Recent reviews have highlighted its effectiveness in improving outcomes for both adults and children experiencing a range of mental health problems and their families (McFarlane, 2016; Brady et al., 2016; Fristad & MacPherson, 2014; Lucksted et al., 2012).

Psychoeducation is associated with a *positivistic* approach, suggesting that universal rules for optimal family functioning can be discerned and shared with a family by an expert professional. This approach might be perceived as disrespectful of each family's distinctive culture or as imposing cultural norms, and thus sits uncomfortably with therapists practicing within a *socio-constructionist* paradigm (Bobele, 2004). This wariness of expertise, although valuable to the development of contemporary family therapy (Andersen, Goolishian &

Windermand, 1986; Hoffman, 1993), may have distanced the discipline from mainstream developmental theory and research, which highlights the role of hierarchical interactions in emotion regulation processes (Hill et al., 2014). Additionally, families value education, as it can help reframe views of identified patients, thus reducing family conflict (Gracio, Goncalves-Pereira & Leff, 2016)

Family Domains Therapy

FDT emerges from Hill et al.'s work on family domains (2003; 2014). The word *domain* refers to a subset of social interactions (e.g. parent comforting distressed child) characterised by distinct rules constraining both the parent's and child's behaviour in order to achieve a specific interactional outcome and allow for a shared interpretative frame (Bateson, 1972). Hill et al. outline four family domains (2014). Three domains (attachment, safety and discipline/expectation) require a hierarchical parental response to regulate the child's emotion: attachment requires acts of comforting, safety acts of protection and discipline/expectation acts of boundary setting. The fourth domain, exploration, requires a more equal, balanced parental response based on information sharing or play (for family domains theory see Hill et al. 2014).

According to the domains hypothesis, when communication is clear, domains can be *matched* when this occurs parent and child share an understanding of the action they are engaging in (e.g. comforting). Clear communication and domain matching interactions are said to promote emotion regulation and mutual understanding. Domain *mismatch* occurs instead either when parent and child are signalling different domains (e.g. child requests comfort, parent responds with discipline) or when unclear communication signals multiple domains simultaneously (e.g. young person engages in defiant behaviour to elicit parental

comfort). Unclear communication and domain mismatched interactions result in misunderstanding and escalating emotional intensity.

FDT aims to help families track interactions using the domains model and create opportunities to consider and practice alternative communication strategies. It does so by providing psychoeducation to parents on parenting children with mental health difficulties and the emotional and behavioural changes associated with adolescence; explaining the domains model and helping families assess and improve their communication skills and their capacity to identify their child's needs and respond appropriately.

Aims

The aim of this study is to explore the interactional impact of psychoeducation within a first FDT session. The author (SP) examined the data with the following questions in mind: How do therapists deliver psychoeducation? How do families respond to psychoeducation? How do therapists manage the family's response?

Methodology

Conversation Analysis

Conversation Analysis (CA) is an empirical approach that studies how social action[5] is achieved in naturally-occurring everyday interactions (Sacks, Shegloff & Jefferson, 1974). CA explains how people's way of talking demonstrates reciprocal understanding, without the need for the analyst's interpretation (Schegloff, 1997). It does so by exploring in detail, through a sophisticated transcription style, known as Jeffersonian (Jefferson, 1985), all aspects of interaction, even those that seem accidental, irrelevant or ungrammatical (e.g.

[5] Interpersonally oriented verbal or non-verbal behaviour (e.g. "would you like a drink?" accomplishes the social action of offering).

pauses, restarts). CA only accepts empirically observable linguistic and paralinguistic features as evidence for its claims (Madill, 2015).

The aim of CA is to describe the competencies that ordinary speakers rely on when participating in interaction, to uncover their regularities and record how exceptions to these regularities are exploited in order to achieve particular actions (Heritage, 1988). This study relies on CA's methodology and body of knowledge to make claims about interactional practices within the context of FDT sessions.

Data and Participants

The data includes four FDT sessions conducted by three experienced systemic family therapists, with four families (Table 1). Sessions were videotaped as part of a feasibility study into the delivery of FDT to families of young people in receipt of Dialectical Behaviour Therapy (DBT; Linehan, 1993) for self-harming behaviour. Families consented to the use of this data for qualitative process research. Ethical principles of informed consent, right to withdraw, guarenteed anonymity and data protection were followed throughout the research project. All data was collected in the United Kingdom.

In all sessions the families were introduced to FDT for the first time, however P6 was in receipt of family therapy before consenting to the study. All young people were 16 years old and receiving DBT from their local mental health service.

Table 1. Participants

Participant code	Session n	Family members present	Therapists
P2	1	Mum	T1; T3
P3	1	Mum and Young Person	T1; T2
P5	1	Mum and Young Person	T1; T2
P6	7	Mum and Young Person	T1; T3

Analytic Procedure

Sessions were initially transcribed verbatim using elements of Jeffersonian transcription (turn-taking, overlaps, gaps and pauses; see Figure 1 for transcription notation, Appendix 4[6] for transcription sample). As recommended by Schegloff (2007), broad sequences were identified and broken down into smaller sequences (see Appendix 5). Therapist and family members' social actions were established and three FDT-specific therapist strategies were identified (assessment of the family's communication, formulation and psychoeducation) and a sequential map of each session was created (see Appendix 6). Psychoeducation was defined as "the provision of information with the purpose of increasing the family's understanding of the therapy model or the young person's difficulties". Sequences containing psychoeducation were transcribed in greater depth (including paralinguistic features, Appendix 7), collected and analysed in order to identify psychoeducation's function, position and features (Appendix 8). Family responses to therapists' strategies were scrutinised for signs of uptake[7] (Schegloff, 2007) and consistency with the domains model. Therapist's management of family responses was also examined

Reliability, Validity and Reflexivity

Although CA's validity and reliability are grounded in its approach to the data (Sidnell & Stivers, 2013), several additional measures were taken to ensure procedural precision and methodological congruence:

- The analytic procedure was discussed with the research supervisor (MS) and experienced CA researchers.
- A research assistant (KJ) independently corroborated all transcriptions.

[6] Appendix numbering is for the purpose of the thesis manuscript.
[7] A response to a social action that forwards its cause.

- KJ and the main author (SP) independently selected “psychoeducation” sequences. Only sequences agreed upon by both authors were included.
- Extracts of psychoeducation were discussed with the founder of FDT (JH).
- Extracts are provided alongside findings for the reader to judge the plausibility of the claims made.

As the main author (SP), I was aware of a tension between my interest in systemic family therapy and in more directive therapy approaches (e.g. DBT). This tension generated a curiosity regarding the use of psychoeducation in family therapy.

Figure 1. Transcription Key

⟶	Turn-at-talk of interest in extract
bold	Feature of interest in extract
[ ]	Overlapping talk
=	No space between turns
(0.4)	Intervals within or between talk (measured in seconds)
(.)	Discernible silence too short to measure
–	Abrupt cut-off of preceding sound
:::	Extension of preceding sound (the more colons, the greater the extension)
.	Closing intonation (not necessarily the end of a sentence)
,	Continuing intonation (not necessarily between clauses of sentences)
?	Rising intonation (not necessarily a question)
¿	Weak rising intonation
Underline	Emphasis
CAPITALS	Loud, relative to surrounding talk
°word°	Soft, relative to surrounding talk
>word<	Speeded up relative to surrounding talk
<word>	Slowed down relative to surrounding talk
>word	'Jump started' talk with loud onset
↑ ↓	Marked rise or fall in pitch immediately follow the arrow
.hhh	Audible inbreath (the more 'h's' the longer)
hhh	Audible outbreath (the more 'h's' the longer)
hah/heh/huh	Laughter particles
( )	Transcriber could not hear what was said
(word)	Possible hearing of what was said
((word))	Description of sound or non verbal behaviour
.pt	Tongue click

Findings

Preliminary Observations

All sessions presented features similar to psychotherapy sessions, with most topics initiated and terminated by the therapist (Peräkylä, Antaki, Vehviläinen & Leudar, 2008). The therapists attended to three tasks within the sessions: establishing rapport, conducting an informal assessment of family communication and introducing families to the domains model

and the therapy process. In each session families received psychoeducation on the domains model in a therapist-led sequence. Additionally, 24 instances of psychoeducation were identified throughout the remainder of the sessions, around half of which (13) came from P6's session, potentially because this family was known by the therapists and had begun the session by describing a situation which the therapists offered to explore using the domain model. In reporting findings, the main processes of psychoeducation delivery will be initially addressed, followed by an outline of its reception and the therapist's management of this.

Psychoeducation Delivery

All psychoeducation sequences were initiated by the therapist and occupied a *post-expansion sequential position*, meaning they came after a family member had responded to a therapist inquiry, and were structured as a reworking of the family member's response. On two occasions, psychoeducation sequences were initiated by the therapist in order to return the talk to therapy relevant issues after a topic shift; however, even on these occasions they acted to expand a previous sequence. Only the model delivery (i.e. the explanation of the whole therapeutic model) stood out as an independent sequence.

For the most part, the model delivery and other psychoeducation sequences (14) appeared to serve the function of delivering education and clarifying the domains terminology, however, some served secondary functions such as accounting for the therapy process (7), managing potential blame (6), and managing the potential difficulty of requesting that a parent recall specific family interactions (1).

The majority of psychoeducation was delivered as indisputable universal fact that provided explanation for the family's situation. This emerged from the use of the following features[8]:

1. Causal prefaces. The use of prefaces such as "so", "cause" and "because" can indicate a causal connection between the statements of the family and those of the therapist (Figure 2; Bolden, 2006).

Figure 2. Causal prefaces.

[P6:1043] T3: **cause** of course when you're (0.3) °worried about somebody° (.) °harming themselves¿° (0.4)

[P5:452] T2: **so** that's like kind of (.) e:rhm: (0.8) pt (0.3) that's where the domains are a bit unclear¿

2. Lexical choices. Use of *evidential markers* (terms that suggest the evidence of statements) such as "obviously" and "of course" imply that any alternative to the statement is inconceivable (Stivers, 2011). This contributes to presenting psychoeducation statements as indisputable facts (Figure 3).

Figure 3. Evidential markers.

[P6:1043] T3: cause **of course** when you're (0.3) °worried about somebody° (.) °harming themselves¿° (0.4)

[P2:300] T1: >because **obviously**< .hh °when: young people have been erhm injuring themselves over a period of time°

3. Membership category devices (Sacks, 1992) and the unspecific "you" (Figure 4). The use of category type terms (e.g. "young person", "parent") and "you" used as

[8] Note: more than one feature can appear in the same turn-at-talk.

unspecific "one" (as in "one wouldn't do this") construct psychoeducation into something general which everybody experiences, serve a normalising function and convey universality of the facts described (Halonen, 2008).

Figure 4. Membership category devices and unspecific "you".

[P6:1043] T3: cause of course when **you're** (0.3) °worried about somebody° (.) °harming themselves¿° (0.4)

[P6:726] T1: >sometimes a **parent** can say to a: **young person**

4. "Granular" accounting or conversational strategies that increase the listener's access to reported events by becoming more detailed (Schegloff, 2000). These strategies convey the factual reality of what is being reported by painting a vivid picture of it. They involve the use of the *-ing* form, the use of reported speech, and visible behaviour (Figure 5)

Figure 5. Granular accounting.

[P6:907] T3: >there is a possibility< that that might flip (0.3) >{YP's name} goes< **((T3 claps hands))** (.) **"oh I'd like to be back at,** (1.1) **((T3 slaps own knee)) half twelve".**

Note: in this extract T3 uses non-verbal behaviour to perform the telling of what appears to be an *extreme case formulation* (Pomerantz, 1986).

However these statements of facts were delivered tentatively by therapists. This was evidenced by:

1. Epistemic markers (Figure 6; linguistic structures that indicate a stance towards evidence) such as "I guess" and "I suppose". These are considered to display a weaker form of knowing and invite the listener's stance (Kärkkäinen, 2006). Other markers

such as “you know” delivered in psychoeducation sequences seemed to appeal to shared knowledge as a means of pursuing an agreement (Asmuss, 2011).

Figure 6. Epistemic markers.

[P2:567] T1: very quickly (0.2) events can take us from: (.) one domain to another (.) very rapidly. .hh and **I guess** if it isn’t kind of clearly comm[unicated,](0.3)

[P2:740] T3: **I suppose** what we we’d say, (0.4) that might be a: e:rhm (.) .hhh a kind of (.) safety conversation

[P6:907] T3:you can have a conversation abo:ut (0.5) **>you know<** (1.1) ehm **you kn-** you can have and exploratory conversation about a decision,

2. Person references (e.g. “we” and “us all”) to refer to both family members and therapists. These seemed to assume the mutual acceptance of a notion being shared (Figure 7; Sacks, 1992).

Figure 7. Person References

[P6:820] T3: when (0.3) **we** communicate clearly (0.4) between **us we’**re less confusing,

[P2:567] very quickly (0.2) events can take **us** from: (.) one domain to another

3. Turbulent delivery patterns (restarts, drawn out words and pauses) add a tentative feel to the delivery of the therapist’s statements (Figure 8; Silverman, 1997).

Figure 8. Turbulent delivery pattern.

[P5:452] T2: so that's **like kind of (.) e:rhm: (0.8) pt (0.3)** that's where the domains are a bit unclear¿

[P2:740] T3: I suppose what we we'd say, (0.4) that might be **a: e:rhm (.) .hhh a kind of (.)** safety conversation

4. Modal verbs such as "can" or "might" act as indices of uncertainty thus conveying tentativeness to assertions (Figure 9; Heritage, 2013).

Figure 9. Modal verbs.

[P3:512] T2:so you might (0.7) your mum **might** be trying to make sure you're safe and you **might** be f-(0.4) be (0.2) being feel (.) felt like you're being told off

[P2:740] T3: I suppose what we we'd say, (0.4) that **might** be a: e:rhm (.) .hhh a kind of (.) safety conversation

5. Vague references such as "sometimes" or "something" can function to avoid accountability (Figure, 10; Potter, 1996).

Figure 10. Vague references.

[P6:1043] T3: cause of course when you're (0.3) °worried about **somebody°** (.) °harming themselves¿° (0.4)

[P5:471] T1: **sometimes** ou:r [facial expression] [can look] **something else** ca[n't it] really

Less commonly, psychoeducation was delivered directly with prescriptive language. This was mostly achieved by referring directly to a family member using the person reference "you", describing a course of action or experience which is in the domain of knowledge of

the family member, using a *reverse polarity question tag*, a negatively formatted question at the end of a sentence to convey an assertion (e.g [P6:595] `T1: you moved into a different domain didn't ya.`; Koshik, 2005) or using a negative formulation which conveys the potential complainability of a certain course of action (e.g. [P2:740] `T3: >cause you wouldn't (run in into)< >you wouldn't be doing it in the moment would you`). This can be a problematic format as it communicates that the therapist has better access to the family member's experience than the family member themselves, it also resembles *known-answer questions,* typical of the classroom environment, where the questioner already knows the answer, and which in a non-classroom setting might be experienced as patronising (Schegloff, 2007).

Psychoeducation was observed to be packaged in the following formats:

a) *Non-technical scenarios* (5 instances) involve the use of often hypothetical examples that do not rely on the technical terminology of the domains model. They were the most likely to be used by the therapists to do other actions than just providing information, such as managing potential blame and accounting for the therapy process. They were often used after the therapist's attempts at describing the therapy process had received minimal uptake from the family.

b) The *"if X then Y" format* (9 instances), is a causal sentence construction, often used with minimal or no technical terminology. It can also appear with "when" replacing the "if" ("when X then Y") and with "then" often being omitted or replaced by "sometimes". This format was occasionally used for the additional action of managing blame or accounting for the therapy process. It was mostly used after the therapist had conducted a communication assessment (i.e. enquiry into the family's communication) and the family had narrated their personal circumstances.

c) The *technical terminology paraphrase* (6 instances), allows the explanation of the domains model terminology. It could present either as a brief insertion into a larger formulation sequence or as a longer sequence comprising of technical term illustration followed by colloquial paraphrase. Technical terminology was prefaced by the sentence "we would call this". Its main action was to deliver education, and each instance followed a different type of interactional sequence, making it impossible to ascertain when therapists most commonly use this type of psychoeducation format.

d) The *formulation format* (4 instances) refers to the use of technical domains terminology within a formulation (Antaki, 2008). These sequences were characterised by direct, non-tentative and prescriptive language. Their main action was to deliver psychoeducation. This format was used after the family had provided an account of personal circumstances following a communication assessment, formulation or other psychoeducation sequence.

e) The *model delivery* refers to the presentation of the domains model over a long therapist-dominated sequence lasting between four and seven minutes. These sequences all presented with a similar structure that involved the introduction of a technical term followed by a non-technical paraphrase and the provision of several examples, using similar conversational strategies as the other psychoeducation formats.

There is an available literature on the use of scenarios and formulations to provide explanations and generate uptake and the risks of using direct language within them (Gülich, 2003; Peräkylä et al. 2008; Couture & Sutherland, 2006), for these reasons only formats b), c) and e) will be explored in more depth below (see Appendix 9 for examples of non-technical scenarios and formulation format).

"If X then Y".

In extract 1, the mother (M) has just spoken about how she tries to approach her daughter calmly yet her expression might give away her panicking state. This can be seen as an FDTconsistent statement as it implies a potential area where domains are not clear.

Extract 1. [P5:471] "if X then Y"

1	T1:	is that (i- is that) (.) cause you: might be worried.
2	M:	yeh
3	T1: →	>and I guess< (0.2) for any of us if we're worried
4		sometimes ou:r [facial expression] [can look] =
5	M:	((nods)) [y:eah]
6	T1:	= something else ca[n't it] really
7	M:	((nods))[y:eah]((nods))

After an initial understanding check from the therapist (T1; line 1) which is confirmed by M (line 2), T1 uses psychoeducation to corroborate M's previous statement and imply that an emotional state might make interactions less clear. He does so using an "and" preface (line 3), which suggests that he is merely extending M's talk (Antaki, 2008), then creates a tentative yet universal general truth by using the tentative knowledge marker "I guess" and the statement "for any of us", alluding to a common experience between family members and therapists. Then T1 begins the "if X then Y" format (line 3). Once again he alludes to common experience by the use of "we" and "our" (lines 3-4), introduces tentativeness with the adverb "sometimes" (line 4), which takes the place of the more factual "then" in the "if X then Y" format, and the use of "something else" (line 6) which introduces a vagueness to what facial expressions might look like and avoids the idea that facial expressions might be wrong or misleading. The psychoeducation statement is then concluded with a negatively formatted polar tag question, as in a question added at the end of a sentence that suggests a

"yes/no" answer and is commonly used to elicit alignment with the speaker's stance (Stivers, 2010).

Technical terminology paraphrase.

Extract 2 is a typical technical terminology paraphrase. It occurs after a previous topic shift initiated by the young person (YP) in which he has described his school curriculum.

Extract 2. [P6:503] Technical terminology paraphrase

```
1   T1: ⟶ pt .hh so if you were thinking in terms of domains,
2           (0.6) you: and {YP's name} (0.2) are kind of doing,
3           (0.2) >you've noticed you're doing a lot more of what
4           we would call the,< (0.4) exploratory conversations.
5   M:      um hmh= ((nods))
6   T1: ⟶ =trying to to work out,
7   (2.2)((M nods))
8   T1: ⟶ where each is coming from,
9   (0.7)((M nods))
10  T1:     yeah?
11  (.)
12  T1:    >would you agree with that?
13  (1.6) ((YP and M nod))
```

The tongue click and inbreath (line 1) are turn taking markers as the previous turn has come to an end and either therapist could select the next topic (Schegloff, 2007). The preface "so" in this case is known as a "resumptive so" which occurs after a sequence has ended and it indicates that talk is returning to a previous topic (Raymond, 2004). The turn continues with "if we were thinking in terms of domains" (line 1) which differs from the "if X then Y"

format, as it is not intended to causally link two sentences but rather to forewarn the family that what is coming is a technical paraphrase or a more educational statement. In line 2 the psychoeducational statement begins with direct reference to the family's experience - "you and {YP's name}" – suggesting that this educational statement is more directed towards M than YP. T1 then takes a direct stance with the use of "you're kind of doing" (line 2) which however is then repaired into "you've noticed you're doing" (line 3). This gives the agency of the psychoeducation back to the family, by suggesting that they have done the noticing, not the therapist. "what we would call" (line 3) prefaces the technical term "exploratory" (line 4). In this instance, use of "we" suggests asymmetry between "we" (the therapists) and "you" (the family). The final intonation in line 4 suggests the therapist's sentence is complete (Goodwin, 1979); however, T1 continues following a minimal acknowledgement from M and provides a colloquial paraphrase of the term (lines 6 and 8). This also meets minimal acknowledgement and leads into two polar tag questions (line 10 and 12) which again fail to generate a more solid uptake.

Model delivery.

Due to the length of the model delivery sequence, it is not possible to reproduce an example here. However, unlike the formats above, model delivery was often preceded by a pre-sequence (a sequence requesting the family's permission to describe the model), which showed the concern the therapists had with managing the impact of taking such a long turn (for function of pre-sequences, see Schegloff, 2007). Additionally, therapists demonstrated discomfort with model delivery that they did not show in the formats described above. This was manifest in the laboured nature of model delivery, which was marked by frequent restarts and apologies from therapists with regards to length of delivery, style and terminology (Figure 11).

Figure 11. Therapist discomfort with length, style and terminology of model delivery.

[P2:408] would t be useful >if we if y' kind of y' you're prepared to listen to me for about< (.) FIve minute[s and (inaudible)y]eah?)

[P6:319] T1:I don't want to sound anything like school °>or anything like that {YP's name} you know<°),

[P3:231] T1: we think there's only four domains (0.3) er I- I know it's >°a bit a (ba-)°< can't- >we can't think of a better word< y[eah?].)

[P5:154] T2: so- (0.4) ↑o↓kay so it's a framework >↓we call it a framework< (1.04) >°don't know why we call it a framework (.) why do we call it a framework¿°<

Psychoeducation reception

The reception of psychoeducation in this study closely resembles findings in the CA literature on responses to medical diagnostic statements: approximately two thirds of responses consisted of silence, nodding, minimal or token acknowledgements (e.g. "yeah", "um hmh", "hm", see extracts); whilst only one third consisted of marked acknowledgements (Heath, 1992; Peräkylä, 2002). Marked acknowledgements included: a) assessments that provided a straight agreement with the therapist's statement (e.g. [P2:278] [y' ex]actly; Pomerantz, 1984), b) collaborative completions, meaning the family member's completion of the therapist's turn-at-talk (Sacks, 1992), and c) extended responses providing evidence for agreement. Extended responses not only display the family member's acknowledgement of the receipt of information, they also allow the therapist to assess the family member's

understanding of psychoeducation (Schegloff, 1984). No open disagreements were present in this database. Considering the aim of FDT to increase the family's ability to use the domains model, the production of extended responses is crucial, for this reason they will be analysed in more depth.

Extended responses.

Extended responses occurred in 8 instances. Four occurred during or after model delivery, three in response to non-technical scenarios and one in response to an "if X then Y" statement. They all involved a further telling of the family member's circumstances that revealed their understanding of the therapy model.

In extract 3 we can see an "if X then Y" psychoeducation statement tagged onto a non-technical scenario. In this case "if" has been substituted with "when" (line 1) and, as in extract 2 "then" has been substituted with "sometimes" (line 5). T2's statement contains many of the features described above and some technical terminology (lines 5-6) and a hypothetical non-technical scenario as well (lines 7-10). M's response (line 11) is extended, and provides more information about her own experience, as noted by the contrastive stress on "I" (Peräkylä, 2002). This is followed by an account of her behaviour, prefaced by "because" (line 11) and also by the consequences of this behaviour, prefaced with "so" (line 12). This response, if interpreted using the FDT model, is considered model consistent as it implies that M's worry about YP (safety domain) is allowing YP to trespass rules (discipline/expectation domain). T2 receives this information as newsworthy, as indicated by the stretched "ah" and the receipt token "okay" (line 14; Heritage, 1984). From an FDT perspective M then continues to elaborate suggesting further lack of domain clarity, by implying that her desire not to upset YP (attachment domain) accounts for her lack of enforcement of discipline. M then completes her turn with an "turn-ending so" (Raymond,

2004). This later (not shown in transcript) leads into a self-realization statement from M that maybe she needs to be "more strict" (potentially clearer in the discipline/expectation domain) and a debate between M and YP regarding the arguments they have at home.

Extract 3. [P3:512] Extended response

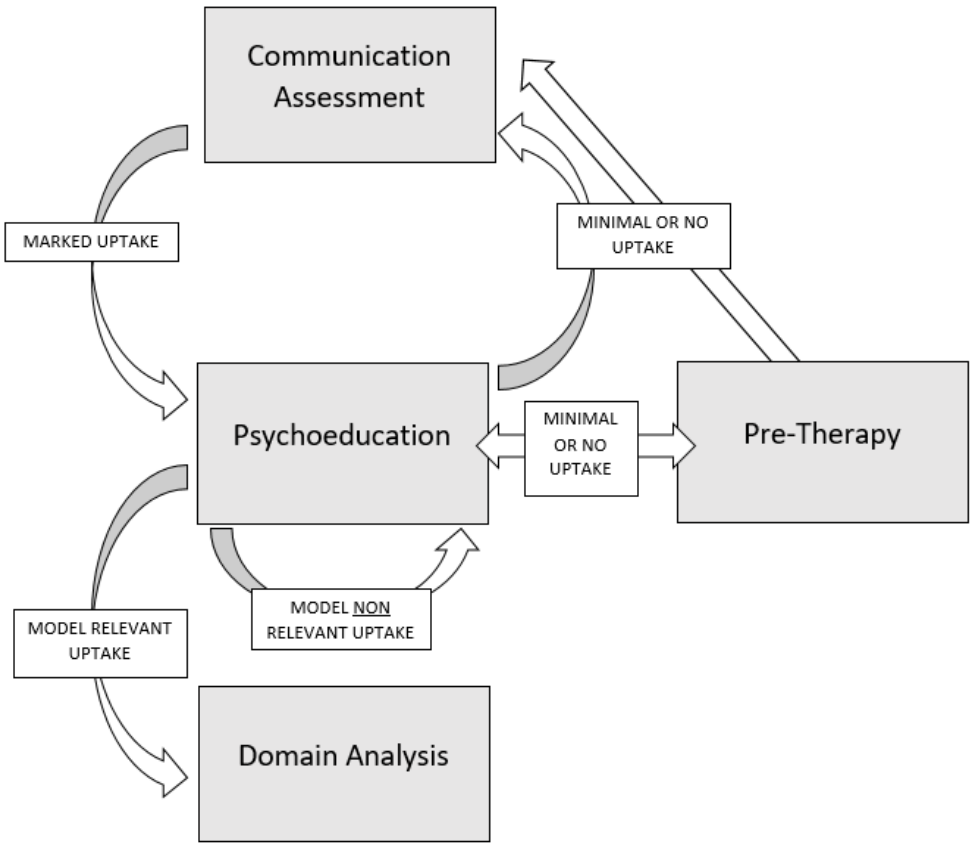
1	T2:	sometimes when people who (0.4) hurt themselves in the
2		past (0.2) a:rgue or (0.2) still h- bang their heads
3		(0.4)
4	YP:	hhhh=
5	T2:	=sometimes the argument's about (.) around SAfety
6		(0.5) and safety and discipline (.) domains can get a
7		bit mixed up so you might (0.7) your mum might be
8		trying to make sure you're safe and you might be f-
9		(0.4) be (0.2) being feel (.) felt like you're being
10		told off does that make sense?=
11	M: ⟶	=pt I try not to shout at her because (.) I worry
12		about her doing something to herself, that's .hhh so
13		she gets away with quite a lot [really.]
14	T2:	[↑a:::↓]:h okay
15	M: ⟶	pt (0.7) cause I don't like (0.6) I don't like
16		up↑setting her ↓so, (.) hhhh
17	(0.9)	

Therapist Management of Family Response

The therapist's response to the family's marked agreements depended on whether they were model consistent (i.e. displayed understanding of the model). If model consistent the therapists would then suggest the family provide an example of a difficult interaction to analyse using the domains model (i.e. domains analysis). If not model consistent, the therapists would re-issue a psychoeducational statement.

Therapist's response to silence, nods and minimal uptakes was more complex. During the model delivery, therapists often responded by merely continuing with the model delivery. However, in other instances of psychoeducation therapists responded either by orienting the family to the therapy process (i.e. pre-therapy), or by inquiring about the family's communication (i.e. communication assessment). However, most pre-therapy sequences did not lead to uptake, and therapists resorted to returning to communication assessment enquiries, which more readily elicited responses from family members. This movement between different strategies (Figure 12) presents some similarities with previously proposed *step-wise entry models* to practices such as advice-giving (Heritage & Sefi, 1992; Couture & Sutherland, 2006).

Figure 12. Process of delivery of psychoeducation in Family Domains Therapy.



Key: Grey boxes = therapist actions; White boxes = family member's actions

Discussion

Findings suggest that psychoeducation in a first FDT session is usually delivered as a reworking of family members' responses to a previous therapist action, a feature it shares with formulations (Antaki, 2008). When delivering psychoeducation, therapists balance the presenting of information as factual and universal with a tentative style that invites the family's response, a feature also common to doctor-patient interaction (Peräkylä, 2002). Different formats for the delivery of psychoeducation were observed, which closely resembled those used for the delivery of medical information to non-experts (Gülich, 2003).

Non-technical scenarios and "if X then Y" formats were more likely to elicit extended responses from family members. There could be several reasons for this. Firstly, it is possible

that family members withhold responses from psychoeducation that contains technical language as the use of technical language orients them to a fundamental asymmetry between the therapists' knowledge and their own; this is observable in the use of "we" in the sentence "we would call this exploratory domain", which indicates a difference between "we" therapists and "you" family. This asymmetry could lead to family members subordinating their knowledge concerning their young person's difficulties, as their interaction with the therapist becomes that between a non-expert and an expert who holds the "objective, scientific, factual assessment" of their difficulty (Heath, 1992, pg 264). Secondly, family members might be hesitating to respond so as to encourage further elaboration from the therapist as to the treatment implications of the psychoeducation (Maynard, 1997). Thirdly, psychoeducation delivered in non-technical language is potentially better *recipient designed*, or couched in a language that is within the family's experience, therefore providing opportunities for family members to use the language they know (Sacks et al., 1974). Lastly, presenting psychoeducation in a scenario format could have a different *sequential implication*, that is because of their storytelling-type features, scenarios might imply that an extended answer is expected of the family. In fact, preferred answers to storytelling involve a reciprocal story which endorses the speaker's stance whilst preferred answers to information-giving merely require the listener to mark the information as newsworthy (Schegloff, 2007). Thus, psychoeducation couched in a scenario or story format might be more successful in eliciting extended responses from the family.

It was additionally observed that therapists displayed some discomfort with delivering the more technical domains model. This could be due to a lack of familiarity with delivering psychoeducation, the novelty of this approach and therefore an uncertainty as to how to deliver the information or a professional discomfort with overtly taking an expert role.

Therapists are potentially more used to delivering non-technical psychoeducation in their day-to-day practice, and might not even recognize it as such. This is consistent with reports suggesting that "non-expert" practices conceal rather than remove the therapist's authority (Guilfoyle, 2003).

The findings from this study question the utility of delivering technical psychoeducation, as this format never received more than minimal uptake. Additionally family members rarely used the technical terminology (3 instances). It is possible that the technical terminology may be perceived as too distant from the family's experience and might ultimately interfere with rapport building. Nonetheless, our data only reflects the first session of FDT. Potentially, as sessions progress families might integrate the domains language into their speech. Further research into later sessions and into family's opinions about the technical terminology might clarify this.

Issues of generalizability and sampling are often raised in qualitative research. These findings are limited to this context and the aim of this paper is not to generalize about all psychoeducational settings but merely to analyse the impact psychoeducation had on these interactions. It could also be questioned whether this data could be considered as *naturally occurring* as it was produced within a feasibility study; however, arguably this data *naturally occurred* within a feasibility study, a common type of study for testing novel interventions. To broaden these findings, future research could be conducted in well-established psychoeducational programmes to search for potential similarities in its delivery and receipt.

Hopefully, this study can provide reflections on the delivery of FDT psychoeducation, prepare practitioners for potential family responses and highlight dilemmas that all therapists might experience when they approach psychoeducation for the first time, such as discomfort with terminology or deciding which format to use.

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CONTRIBUTIONS TO THEORY AND CLINICAL PRACTICE

Introduction

Conversation Analysis (CA), a methodology developed within the sociology tradition, has been welcomed as an ideal approach for the study of process in the field of psychotherapy (Gale, 1991; Strong, Busch & Couture, 2008). The work so far presented has reviewed the use of CA within the field of family therapy and then provided an example of how CA can be used within the context of a feasibility study of Family Domains Therapy (FDT) to explore how psychoeducation was delivered, how families received it and what therapists did to manage the family's responses to it. In the following paragraphs further reflections on the implications of this work for future research, theory development and clinical practice will be outlined, as well as the author's reflections on the process and impact of conducting this work.

Conversation Analysis and Family Therapy Process Research

Process research addresses the question of how psychotherapy works: what happens within the client-therapist system that somehow enables change to occur. Its aims include: a) to deliver empirical evidence for the way in which therapy processes bring about change; b) to contribute to theory development by identifying moments when practice diverges from theory; c) to improve the quality of therapy by underlining which aspects of treatment are the most important in effecting change; d) to assist in the development of effective training (Hardy & Llewelyn, 2015). CA can be considered a micro-analytic sequential process research design and is only one of many potential process research methodologies (Elliott, 2010). In the context of psychotherapy process research the use of CA methodology is aimed at investigating the "direct, immediate influence of therapeutic interventions on within-session client processes and also the effect of client actions on the processing and planning activities of the therapist" (Elliott, 2010, pg 128). The literature review presented in this

manuscript collated all available literature in the field of family therapy process research which used Conversation Analysis (CA) as a methodology, whilst the empirical paper provided an example of how CA can be used to study family therapy process. The following paragraphs will present a discussion of how CA can meet the aims of family therapy process research in the light of the research conducted in this manuscript. These will be divided according to implications for future research and theory development and implications for clinical practice.

Implications for Future Research and Theory Development

Can CA deliver empirical evidence for the way in which family therapy processes bring about change?

There is no straightforward answer to this question. Within the literature reviewed in this manuscript only Couture and Sutherland's work (Couture, 2006; 2007; Couture & Sutherland, 2006) directly addressed moments of change and how the therapist's strategies aided that change. Even the empirical paper presented here, like most of the literature reviewed, was directed to exploring the use of a particular therapeutic strategy rather than specific change events.

CA as a methodology can provide in-session evidence to show what people make of therapists' proposals, whether they agree with them, whether they reportedly change their understanding of their own experiences or change their behaviour (Peräkylä, Antaki, Vehviläinen & Leudar, 2008). However, demonstrating change in session does not necessarily translate into post-therapy outcome nor can it account for processes that extend beyond the immediate preceding response, for example how previous therapy sessions influence people's responses in later sessions (Elliott, 2010). This does not mean that CA cannot be integrated with other research approaches such as process-outcome research

(Orlinsky, Rønnestad & Willutzki, 2004), or the significant event process research approach (Elliott, 2010), or that it cannot provide a stepping stone for further research (see below). Currently, CA is being integrated with quantitative approaches in order to provide statistical evidence of how certain interactions lead to specific responses (Heritage, 1995; Heritage & Roth, 1995). Therefore, CA can successfully be integrated with other approaches to deliver empirical evidence on processes that bring about change.

However, in order to identify which change processes to explore in more depth and where to direct future research, it is important to identify gaps in the literature and this can only be done by collating studies and accumulating knowledge. One observation that emerged from reviewing the CA literature in the field of family therapy is its heterogeneity. This was manifested not only in the different methodological producers of the studies reviewed but also in the number of studies that were excluded, either because they made no reference to CA yet relied on its body of knowledge or because they made reference to CA yet did not use extracts, Jeffersonian transcription or naturally occurring data. At the moment, the CA literature in the field of family therapy but also psychotherapy more generally provides many micro-snapshots of practice but no clear picture of how different psychotherapeutic process interlink (Peräkylä et al., 2008). For it is only by collating findings into a map of psychotherapy process that one can identify what gaps there are in the literature and how to fill them (Hardy & Llwelyn, 2015; Elliott, 2010).

Can CA contribute to theory development by highlighting when practice diverges from theory?

Each different school of psychotherapy considers some interactional practices between therapists and clients to be the ones that promote change in the patient's mind, behaviour and social interactions (Peräkylä et al., 2008). CA can offer a tool by which these

practices can be observed and systematically analysed in order to assess the strength of theoretical claims. However, this process is potentially exposing and requires curiosity and willingness to challenge previously held assumptions. In the literature review, for example, it was observed that this type of "theory-challenging" CA was rarely conducted, most research was exploratory with the intent of providing advice on the best way to conduct an already established practice, without questioning the practice itself. Exploratory type research can lead to the discovery of previously untheorized practices (see Gale & Newfield, 1992; Parker & O'Reilly, 2013; Couture, 2006; 2007; Couture & Sutherland, 2006) which can then be assimilated within existing theoretical frameworks, but it is quite different to set up a research design to challenge a theoretical assumption.

For example, in the review of CA literature in the field of family therapy, collaborative strategies were often explored and it emerged that these strategies were more likely to lead to uptake from the family whilst directive strategies were more likely to lead to entrenched responses (Couture & Sutherland, 2006). Future research could explore in what circumstances collaborative strategies do not lead to uptake, in what circumstances directive strategies are more likely to engender uptake, whether collaborative strategies are used to conduct similar functions to directive strategies, or in what contexts do collaborative therapists resort to directive strategies or directive therapists resort to collaborative strategies. This type of research would create a much broader and comprehensive picture of the impact of designing interventions in a directive vs collaborative way within a family therapy session; to do this, however, would require a critical approach to theory development. Recent theoretical development in family therapy has focused on collaborative approaches within a "socio-constructionist" paradigm that rejects taking an "expert" position towards family's problems in the pursuit of supporting families in finding out their own ways of solving problems rather than imposing them from above (Hoffman, 1993; Andersen, Goolishian and

Windermand, 1986). Challenging this theoretical assumption is potentially a threatening process, especially for clinicians who have adopted "socio-constructionist non-expert" approaches as a moral choice rather than an evidence-based approach (Parker, 1999).

The empirical paper presented in this manuscript provided an example of how underlying therapeutic assumptions can be explored by using CA-based process research. The therapeutic intervention under scrutiny was Family Domains Therapy (FDT) a novel approach in family therapy which relies on the delivery of psychoeducation to support families in the application of the family domains model in their day-to-day life in order to improve interactions. FDT psychoeducation was therefore a novel and key feature of this approach and worthy of exploration. CA methodology allowed the investigation of the second-by-second unfolding of the FDT sessions and the description of the actual interactional patterns and practices through which psychoeducation was delivered. What emerged was a complex picture: psychoeducation was presented in several formats, some more likely to lead to uptake from family members than others, some used for functions other than educating and some with which the therapists presented as less comfortable.

The findings from the empirical paper also suggest that directive strategies are more likely to be met with minimal acknowledgement, however this is not sufficient to suggest that the families do not take in the information or use it, merely that in the conversation they do not find it interactionally significant to respond in any other way. Future research utilizing different qualitative methodology could explore families' experiences of receiving information about the domains model in their first session of FDT or later on or whether they find themselves using those concepts in their day-to-day lives. Additional CA research could be conducted in subsequent FDT sessions to observe whether families take up the domains language and demonstrate their ability to apply it in their recounting of previous interactions. Finally quantitative research could illustrate whether after FDT families have a better

understanding of communication or the domains model, whether they experience improved interactions with their young people or less confusing or "mismatching" interactions, and whether this has an impact on other well-established psychological constructs such as expressed emotions (Hooley, 1985) or on the young person's symptomatology or relapse rate. To further explore the use of psychoeducation in therapy settings these findings need to be compared to how psychoeducation is delivered in other settings (e.g. family therapy with adults or young people diagnosed with schizophrenia or depression or anorexia nervosa, etc.) and in other therapy models (Cognitive-Behavioural, Structural Family Therapy, Dialectical Behaviour Therapy, etc.). This type of research would highlight whether similar formats of psychoeducation are used and whether they receive the same type of responses.

Although further research is needed to comment on the use of psychoeducation in therapy sessions overall, two observations can be made from the empirical study that have direct implications for FDT theory development. Firstly, the way family therapists responded to uptake and lack thereof suggests that they might be pursuing a "step-wise" entry into psychoeducation. The concept of "step-wise entry" is a process initially observed in the practice of advice giving. It involves ascertaining that the family identifies a problem, identifying attempted solutions, and then providing advice (Heritage & Sefi, 1992). In a similar fashion FDT therapists would often identify that the family had a problem via a communication assessment, before offering psychoeducation of the "if X then Y" format, and then when the family displayed model-consistent uptake move onto the main task of FDT which is helping the family conduct a domain analysis. This observation was fed back to the treatment team in the form of a template of how to introduce psychoeducation in a first session of FDT in order to maximise model-consistent uptake from the family. Recommendations included, commencing with a communication assessment, moving onto non-technical psychoeducation and only in the face of model-consistent uptake proceeding

into technical psychoeducation and domain analysis. Secondly, observations regarding the therapists' discomfort with technical terminology raised the issue of taking an "expert position". Delivering technical terminology requires a position of "expertise"; however, when combined with the therapists' usual tentative stance this could potentially lead to a "therapist domain mismatch", in other words the family might become confused as to whether the therapist wanted to explore the meaning of the psychoeducational information for them or explain to them the reason for their difficulties. This suggested that a potentially under-theorised aspect of FDT regards which domains are enacted within the therapy session. Are the therapy domains the same as the family domains? Does the therapist-family system replicate the family's lack of domain clarity in the same way that it tends to replicate the family's communication strategies (Dallos & Draper, 2010). This observation was discussed with the originator of FDT and later the treatment team.

In summary, CA can aid the identification of anomalies, gaps and contradictions in the practice of family therapy, which can open up avenues of future research and aid theory development. The impact on theory development for the empirical study here presented was potentially aided by three contextual factors: a) it was conducted in the context of a feasibility study for a novel intervention; b) the originator of the therapy model was involved in the process of drafting a manual for the intervention; c) the originator of the therapy model and the treatment team were involved in discussions over the findings. It is arguably much harder to challenge theoretical assumptions underlying schools of psychotherapy that have been practicing for over fifty years.

Implications for Clinical Practice

Can CA improve the quality of family therapy by underlining which aspects of treatment are the most important in effecting change?

Unlike other research methodologies which offer clinicians statistical evidence of the efficacy of therapy protocols or insight into the views of a subgroup of service users, CA research provides clinicians with observations on the actual moment-by-moment conducting of therapy. It has been argued that by generating accounts of how therapists and family members use language to negotiate certain social actions, CA can aid the development of "stocks of interactional knowledge" (SIKs; Peräkylä & Vehviläinen, 2003); in other words CA can allow for the collection of normative models of how professionals can interact with family members in order to operationalise theoretical models or frameworks that underpin their professional activity (Antaki, 2008). Practitioners familiar with this literature can move beyond question formats in their understanding of how to deliver therapy, orient toward micro-expressions of partial uptake from family members, and become more aware of taken-for-granted conversational practices that family members might use (Couture, 2006; 2007).

Therefore, CA literature can orient practitioners towards ways of delivering therapeutic interventions so to maximise the possibility of in session "small-o outcomes" and become aware of subtle markers of uptake or disagreement in order to fine tune their intervention (Pinsof, 1988). For example, the literature review highlighted the most effective strategies for interrupting a session in order to consult a reflective team without creating a disruption in therapeutic alliance (Parker & O'Reilly, 2013), or showed how an expert therapist would help move a family from an impasse to a solution (Couture, 2006; 2007; Couture & Sutherland, 2006). In the empirical paper it emerged that psychoeducation

delivered through non-technical scenarios was more likely to lead to extended uptake. These findings can suggest which practices lead to micro-outcomes.

Such findings can help clinicians practicing in similar settings, however they are limited by their context, use of small unrepresentative samples and lack of a broader research project aimed at exploring these features in other settings with different populations. Nonetheless, CA findings in the field of psychotherapy can always be integrated with findings in the wider literature. For example, findings from the empirical paper regarding the frequency of minimal or no uptake to psychoeducation delivered in a technical language appear to reflect findings regarding responses to receiving medical information in primary care settings (Peräkylä, 2002). In psychotherapy both therapist and client rely on everyday language resources to communicate, therefore broader findings of CA literature could be used to expand the current psychotherapy-specific literature.

In summary, the CA literature in family therapy process research can offer clinicians "sign posts" to specific processes (Couture, 2007). In other words CA findings can orient family therapists to certain processes (e.g. disengagement, psychoeducation, joining) and provide suggestions on the possible ways to proceed and possible consequences. In this way it can improve the quality of the delivery of family therapy by improving the clinician's awareness of these processes and the potential possible interactions that may arise from them rather than by pointing out which specific feature of talk or interaction leads to which outcome with certainty.

Can CA assist in the development of effective training?

As mentioned above one way in which CA can improve the quality of the delivery of family therapy is by improving clinicians' awareness of conversational details. This can be achieved in several ways. Firstly, the collection of CA findings, as attempted in the literature

review can provide a platform for a broader audience of clinicians. Secondly, some researchers have advocated for CA-informed reviews. These would involve a trainee professional examining a video-clip of their interaction with a patient or service user together with a CA-informed educator in order to both "look or listen for critical junctures, and examine what is happening sequentially or on a turn-by-turn basis that may have gone well or badly" (Maynard & Heritage, 2005, pg 428). Given that the use of audio or video recording is now a requirement within the British Psychological Society (2016) and the Association for Family Therapy and Systemic Practice in the UK (2015) guidelines for training. CA could provide a methodology to aid the joint analysis of the video between trainee and educator and ground it in the broader CA body of knowledge. Thirdly, CA can be used, as in the empirical paper here presented, within the context of the drafting of a manual for a novel intervention. Not only can CA provide a transcription style that truly represents the "messiness" of therapy rather than a polished theoretical construction that is far removed from the practitioner's experience, but it can help refine advice to practitioners on how best to introduce specific actions like psychoeducation or advice (Couture & Sutherland, 2006) in a specific therapeutic context.

Finally, the conducting of CA-informed research can ground clinicians in its methodology and give an appreciation of its complexity as well as turn their attention to micro-processes (Elliott, 2010). However, when encouraging clinicians to engage in this type of research one must proceed with caution. The terminology of qualitative research (see Appendix 3) and the vastness of the CA body of knowledge can be disorientating and overwhelming for a practitioner and severely limit their ability to utilize CA findings and conduct high quality research. In order to support clinicians it is worth considering whether more emphasis should be placed on training practitioners in this methodology and producing procedural guidelines for the use of CA in psychotherapy. This could take the shape of a

targeted publication (e.g. book or journal) providing clear procedural guidelines. Such a resource would have proven invaluable in the context for conducting this research in that it would have provided criteria for what is to be considered CA research in psychotherapy and proposed a procedure to select, transcribe and analyse data.

Such an endeavour could also open up interesting discussions between CA researchers and psychotherapists regarding theories and language utilised in these publications, how best to present findings from multiple CA studies, the benefits and limitations of a CA approach to psychotherapy and whether adjustments need to be made to CA in order to produce findings that are usable for theory and practice development. For although setting procedural guidelines might limit the creativity of researchers in the application of this methodology, it would also allow the collation of findings to proceed more easily.

Reflections

One of the first things that becomes clear to a Trainee Clinical Psychologist during their first experiences of delivering psychotherapy is that the reality of the therapeutic interaction is very far from the clean and edited transcripts one finds in therapy manuals. It was in part this frustration with the reduction of therapeutic conversations to models and flowcharts that led me to approach the field of CA. Here was a methodology interested in the "messiness" of therapy and capable of revealing the interactional consequences of minute aspects of talk. This excitement, however, was often dampened by the daunting task of getting to grips with a completely different way of looking at data, a field of its own which has grown and developed in the last fifty years. It was hard at times not to feel overwhelmed by the sheer volume of the CA body of knowledge. Here I would like to explore a dilemma

that I encountered whilst doing this work and then offer a reflection on the implication this work has had for my own clinical practice.

The dilemma I faced was how to share my findings with the treatment team. As I was transcribing, reading and re-reading transcripts, identifying sequences and family member's uptake to therapist actions I realized how exposing this methodology is for therapists. As a Trainee Clinical Psychologist I am often concerned after a session as to whether I said the right thing, and the timing and formatting of interventions are often the subject of supervision. This methodology exposes all potential deviation from an "ideal" of how therapy should be delivered. I found myself observing expert family therapists seemingly "getting it wrong", missing opportunities to tackle an issue or persevering in the face of repeated lack of uptake from family members. Initially, I wondered how I could feed this back to the treatment team; however, I came to the realization that it was holding an ideal of what therapy "should look like" that generated my dilemma. This process brought me face-to-face with the fact that "ideal" only exists in psychotherapy textbooks and that fallibility is inevitable in the endeavour of therapy. Once this was accepted, it was easier to move on to see those "mistakes" as opportunities to learn about what processes were at stake and how studying those processes might support the therapy team.

Finally, this work has greatly contributed to my own psychotherapy practice. My current work is with young people in an inpatient setting where there are high levels of risk of harm to self and/or others. As I discussed above in the clinical implications, increasing one's awareness of micro-practices of interaction can aid the clinician's ability to assess the young person's position towards what is being done in therapy and ground it in conversational evidence rather than relying on "clinical instinct", and I often wonder if that clinical instinct is in itself our intuitive response to micro conversational practices. More specifically, given the focus of my work on psychoeducation, I have found myself reflecting on how and when I

introduce psychoeducation in therapy sessions. I noticed that I often delivered it as an observation when I thought that what a young person was saying matched a certain model with little reflection on the interactional impact of doing so and the potential misalignment or "closing down" of conversation that such a delivery could potentially engender. On the one hand, I became more and more cautious of psychoeducation, and began to develop the idea of a step-wise entry into psychoeducation described above, noticing that I increasingly preferred waiting for young people to reach conclusions by themselves. On the other hand, where psychoeducation was required (e.g. in the treatment of anorexia nervosa) I would structure a session to deliver and discuss information alone, finding it much easier to present psychoeducation in written format and then invite the young person to discuss their opinions of it. Additionally though, I also became more aware of how psychoeducation can be used within systems (both families and staff teams) that are experiencing unsafe uncertainty due to the risk to young people's lives (Mason, 1993), in order to generate some certainty and therefore some safety. I observed how senior colleagues would use psychoeducation to construct themselves as experts and therefore reduce the system's uncertainty and distress in the knowledge that someone in the room knew what to do about the problem at hand; and how, once safety and some certainty was restored, these colleagues would invite reflections and suggestions from families in an exploratory fashion.

Conclusion

There is great potential for the use of CA within the field of family therapy. Although difficult and time consuming (Elliott, 2010), this methodology can bring several benefits to future research, theory development and clinical practice as outlined above. However, in order to reap some of these benefits there needs to be a wider collaboration between CA researchers and psychotherapists. The biggest danger for CA in this process, would be for the

CA methodology to be stretched beyond its epistemological remit, which would risk discrediting the method itself (Madill, 2015).

To conclude, I believe this methodology has contributed to the development of my own clinical practice in a way that other methodologies might have not. For this and the reasons mentioned above I would welcome more attention being turned towards CA methodology in psychotherapy process research.

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ETHICS APPENDIX

ETHICS APPENDIX I

Bangor University Application for Ethical Approval

Application for Ethical Approval

Project Title: A feasibility study on the provision of a Family Domains Therapy intervention for the parents/carers of self-harming young people undergoing Dialectical Behaviour Therapy in North Wales

Principal investigator: Pethica, Stefania

Other researchers: Swales,Michaela, Jackson,Mike

Pre-screen Questions

Type of Project
D.Clin.Psy. Staff
Further details: This is a larger project part of which will be used for a D. Clin. Psy

What is the broad area of research
Clinical/Health

Funding body
Other please state
Further details: BCUHB Pathway to Portfolio (P2P) funding

Type of application (check all that apply)
Project requiring scrutiny from an outside body which has its own ethical forms and review procedures
Further details: IRAS form has been completed

Proposed methodology (check all that apply)
Other type of research, please specify. Questionnaires and Interviews
Further details: Questionnaires, Interviews, Problem Solving Task, and post-treatment qualitative analysis of therapy video-recordings.

Do you plan to include any of the following groups in your study?
Children
Further details: Young People aged 14 to 18 and their parents/carers

Does your project require use of any of the following facilities and, if so, has the protocol been reviewed by the appropriate expert/safety panel? If yes please complete Part 2:B

If your research requires any of the following facilities MRI, TMS/ tCS, Neurology Panel, has the protocol been reviewed by the appropriate expert/safety panel?
Not applicable (the research does not require special safety panel approval)

Connection to Psychology, (i.e. why Psychology should sponsor the question)
Investigator is a staff member in Psychology (including the North Wales Clinical Psychology Programme). Investigator is a student in Psychology (including the North Wales Clinical Psychology Programme)
Further details: Chief Investigator is Dr Michaela Swales from the NWCPP and Key Researcher includes Stephanie Parks, DClinPsy trainee

Does the research involve NHS patients? (NB: If you are conducting research that requires NHS ethics approval make sure to consult the Psychology Guidelines as you may not need to complete all sections of the Psychology online application)
Yes, NHS IRAS application attached.

Has this proposal been reviewed by another Bangor University Ethics committee?
No

NHS checklist. Does your study involve any of the following?
Any change to, impact on or assessment of, NHS treatment.. Involve research participants identified because of their status as relatives or carers of past or present users of these services.. Involve research participants identified from or because of their past or present use of NHS services. Including participants recruited through these services as healthy controls?. Use of NHS

Staff or resources e.g. recruitment through the NHS, access to Medical records, use of premises etc.

Part 1: Ethical Considerations

Will you describe the main experimental procedures to participants in advance, so that they are informed about what to expect?
Yes
Further details: All participants will receive a Participant Information Sheet and meet with a trained research officer who will describe all procedures in detail.

Will you tell participants that their participation is voluntary?
Yes
Further details: See Participant information Sheet, Assent and Consent Forms

Will you obtain written consent for participation?
Yes
Further details: See Assent and Consent forms

If the research is observational, will you ask participants for their consent to being observed?
N/A

Will you tell participants that they may withdraw from the research at any time and for any reason?
Yes
Further details: See Participant Information Sheet

With questionnaires, will you give participants the option of omitting questions they do not want to answer?
Yes
Further details: See Participant Information Sheet

Will you tell participants that their data will be treated with full confidentiality and that, if published, it will not be identifiable as theirs?
Yes
Further details: See Participant information Sheet, Assent and Consent Forms

Will you debrief participants at the end of their participation (i.e. give them a brief explanation of the study)?
Yes
Further details: See Participant information Sheet, Assent and Consent Forms

Will your project involve deliberately misleading participants in any way?
No

Is there any realistic risk of any participants experiencing either physical or psychological distress or discomfort? If *Yes* , give details and state what you will tell them to do should they experience any problems (e.g., who they can contact for help)
Yes
Further details: 1. Young people taking part in the study will be required to complete additional questionnaires and interviews (see Methodology). This might involve discussing distressing topics. The clinicians delivering said questionnaires and interviews are all trained with working with this population and all of these additional measures are routinely used in other services. To ensure young people are supported throughout this procedure, should interviews and/or questionnaires prove distressing, every young person will have access to their CAMHS clinician following completion of additional measures. Young people will be reminded that they can drop out of the research at any point without being asked any questions. In addition, as a routine part of DBT,

young people will have access to the telephone number of their assigned clinician to contact if they experience distress related to their condition or related to the research procedures throughout their treatment. 2. All young people referred for DBT and their parents/carers will be offered the opportunity to take part in the research project. Within the research project parents/carers will be offered the possibility of accessing a novel intervention: Family Domains Therapy (FDT). Parents/carers who do not opt into the research will still be able to access non-specified family interventions as currently provided by their local services. Participation in research will not affect provision of local services or what young people or parents/carers are offered (treatment as usual). Some distress might be caused to parents/carers from discussing family issues during the FDT intervention, however this would be no different to the potential for distress in other types of family intervention/therapy. The family therapists conducting the FDT intervention are all trained and supervised by the developer of FDT. FDT takes a non-judgemental and compassionate stance towards all family members. 3. A qualitative interview will be conducted with parents/carers only at the end of their involvement with FDT or of their young person's DBT treatment (if parents/carers not involved in FDT). Although discussing family matters may cause some distress commonly people find it helpful to articulate their experience and their point of view. The final interview will allow parents/carers to give their opinion on the treatment they have received and contribute to the development of a novel intervention. Parents/Carers will be informed that they can choose to stop the interview at any time.

Is there any realistic risk of any participants experiencing discomfort or risk to health, subsequent illness or injury that might require medical or psychological treatment as a result of the procedures?
No

Does your project involve work with animals? If *Yes* please complete Part 2: B
No

Does your project involve payment to participants that differs from the normal rates? Is there significant concern that the level of payment you offer for this study will unduly influence participants to agree to procedures they may otherwise find unacceptable? If *Yes* please complete Part 2: B and explain in point 5 of the full protocol
No

If your study involves children under 18 years of age have you made adequate provision for child protection issues in your protocol?
Yes
Further details: See Assent and Consent Forms and Participant Information Sheets. All young people who take part of this research project will be receiving active treatment from the local DBT treatment team. The research team member collecting data will inform participants of limits of confidentiality and should concerns arise report those concerns to the DBT clinician assigned to the case who will then follow standard NHS procedures. Family Therapists delivering the Family Domains Therapy intervention are all local CAMHS clinicians currently working in local CAMHS and will follow standard NHS procedures.

If your study involves people with learning difficulties have you made adequate provision to manage distress?
N/A

If your study involves participants covered by the Mental Capacity Act (i.e. adults over 16 years of age who lack the mental capacity to make specific decisions for themselves) do you have appropriate consent procedures in place? NB Some research involving participants who lack capacity will require review by an NHS REC. If you are unsure about whether this applies to your study, please contact the Ethics Administrator in the first instance

N/A

If your study involves patients have you made adequate provision to manage distress?
Yes
Further details: 1. Young people taking part in the study will be required to complete additional questionnaires and interviews (see Methodology). This might involve discussing distressing topics. The clinicians delivering said questionnaires and interviews are all trained with working with this population and all of these additional measures are routinely used in other services. To ensure young people are supported throughout this procedure, should interviews and/or questionnaires prove distressing, every young person will have access to their CAMHS clinician following completion of additional measures. Young people will be reminded that they can drop out of the research at any point without being asked any questions. In addition, as a routine part of DBT, young people will have access to the telephone number of their assigned clinician to contact if they experience distress related to their condition or related to the research procedures throughout their treatment. All young people will be receiving active treatment for their self-harming behaviour. 2. All young people referred for DBT and their parents/carers will be offered the opportunity to take part in the research project. Within the research project parents/carers will be offered the possibility of accessing a novel intervention: Family Domains Therapy (FDT). Parents/carers who do not opt into the research will still be able to access non-specified family interventions as currently provided by their local services. Participation in research will not affect provision of local services or what young people or parents/carers are offered (treatment as usual). Some distress might be caused to parents/carers from discussing family issues during the FDT intervention, however this would be no different to the potential for distress in other types of family intervention/therapy. The family therapists conducting the FDT intervention are all trained and supervised by the developer of FDT. FDT takes a non-judgemental and compassionate stance towards all family members. 3. A qualitative interview will be conducted with parents/carers only at the end of their involvement with FDT or of their young person's DBT treatment (if parents/carers not involved in FDT). Although discussing family matters may cause some distress commonly people find it helpful to articulate their experience and their point of view. The final interview will allow parents/carers to give their opinion on the treatment they have received and contribute to the development of a novel intervention. Parents/Carers will be informed that they can choose to stop the interview at any time.

Does your study involve people in custody?
No

If your study involves participants recruited from one of the Neurology Patient Panels or the Psychiatry Patient Panel then has the protocol been reviewed by the appropriate expert/safety panel?
N/A

If your study includes physically vulnerable adults have you ensured that there will be a person trained in CPR and seizure management at hand at all times during testing?
N/A

Is there significant potential risk to investigator(s) of allegations being made against the investigator(s). (e.g., through work with vulnerable populations or context of research)?
No
Further details: Lone worker policies will be followed by all researchers conducting one-to-one data collection. Where there are safety concerns regarding a particular parent/carer, they will only be offered to meet the researcher on CAMHS premises.

Is there significant potential risk to the institution in any way? (e.g., controversiality or potential for misuse of research findings.)
No

Part 3: Risk Assessment

Is there significant potential risk to participants of adverse effects?
No

Is there significant potential risk to participants of distress?
Yes
Further details: 1. Young people taking part in the study will be required to complete additional questionnaires and interviews (see Methodology). This might involve discussing distressing topics. The clinicians delivering said questionnaires and interviews are all trained with working with this population and all of these additional measures are routinely used in other services. To ensure young people are supported throughout this procedure, should interviews and/or questionnaires prove distressing, every young person will have access to their CAMHS clinician following completion of additional measures. Young people will be reminded that they can drop out of the research at any point without being asked any questions. In addition, as a routine part of DBT, young people will have access to the telephone number of their assigned clinician to contact if they experience distress related to their condition or related to the research procedures throughout their treatment. 2. All young people referred for DBT and their parents/carers will be offered the opportunity to take part in the research project. Within the research project parents/carers will be offered the possibility of accessing a novel intervention: Family Domains Therapy (FDT). Parents/carers who do not opt into the research will still be able to access non-specified family interventions as currently provided by their local services. Participation in research will not affect provision of local services or what young people or parents/carers are offered (treatment as usual). Some distress might be caused to parents/carers from discussing family issues during the FDT intervention, however this would be no different to the potential for distress in other types of family intervention/therapy. The family therapists conducting the FDT intervention are all trained and supervised by the developer of FDT. FDT takes a non-judgemental and compassionate stance towards all family members. 3. A qualitative interview will be conducted with parents/carers only at the end of their involvement with FDT or of their young person's DBT treatment (if parents/carers not involved in FDT). Although discussing family matters may cause some distress commonly people find it helpful to articulate their experience and their point of view. The final interview will allow parents/carers to give their opinion on the treatment they have received and contribute to the development of a novel intervention. Parents/Carers will be informed that they can choose to stop the interview at any time.

Is there significant potential risk to participants for persisting or subsequent illness or injury that might require medical or psychological treatment?
No

Is there significant potential risk to investigator(s) of violence or other harm to the investigator(s) (e.g., through work with particular populations or through context of research)?
No

Is there significant potential risk to other members of staff or students at the institution? (e.g., reception or other staff required to deal with violent or vulnerable populations.)
No

Does the research involve the investigator(s) working under any of the following conditions: alone; away from the School; after-hours; or on weekends?
Yes
Further details: Potential for researchers to collect one-to-one data (questionnaires and interviews) in the family home. Lone worker policies will be followed by all researchers conducting one-to-one data collection. Where there are safety concerns regarding a particular parent/carer, they will only be offered to meet the researcher on CAMHS premises.

Does the experimental procedure involve touching participants?
No

Does the research involve disabled participants or children visiting the School?
No

Declaration

Declaration of ethical compliance: This research project will be carried out in accordance with the guidelines laid down by the British Psychological Society and the procedures determined by the School of Psychology at Bangor. I understand that I am responsible for the ethical conduct of the research. I confirm that I am aware of the requirements of the Data Protection Act and the University's Data Protection Policy, and that this research will comply with them.
Yes

Declaration of risk assessment The potential risks to the investigator(s) for this research project have been fully reviewed and discussed. As an investigator, I understand that I am responsible for managing my safety and that of participants throughout this research. I will immediately report any adverse events that occur as a consequence of this research.
Yes

Declaration of conflict of interest: To my knowledge, there is no conflict of interest on my part in carrying out this research.
Yes

Part 2: A

The potential value of addressing this issue

Hypotheses

Participants recruitment. Please attach consent and debrief forms with supporitng documents

Research methodology

Estimated start date and duration of the study.

For studies recruiting via SONA or advertising for participants in any way please provide a summary of how participants will be informed about the study in the advertisement. N.B. This should be a brief factual description of the study and what participants will be required to do.

Part 2: B

Brief background to the study

Further details: Background Self-harm includes any act of intentional self-poisoning or self-injury regardless of motivation and, therefore, includes acts with suicidal intent and those without. Self-harm in adolescence is a major public health problem. The behaviour is highly prevalent (occurring in about 10% of adolescents), often repeated and is the strongest predictor of subsequent suicide. Self-harm exacts a distressing toll on young people and their families and is expensive in terms of health and social costs. Young people with repetitive self-harm often fail to achieve in education and go on to have persistent mental health problems. Suicide is the second most common cause of death in adolescence (Patton et al., 2009). Increased severity of self-harm is associated with higher levels of depression, anxiety and impulsivity (Madge et al., 2011), and patients who escalate the severity of their self-harm are at high risk of completed suicide (Carter, Reith, Whyte McPherson, 2005). Strangulation and attempted hanging in adolescents have increased, both of which are strongly associated with completed suicide (Runeson, Tidemalm, Dahlin, Lichtenstein Langstrom, 2010). Amongst young female suicide victims, 81% have engaged in self-harm (Zahl Hawton, 2004). Repetition of self-harm behaviour is common with repetition rates of between 10-15% within a year and up to 42% for follow-up periods longer than a year (Brent, 1997). Longitudinal studies indicate that repeated self-harm in adolescence is not only a risk factor for subsequent suicide but also carries heightened risk of psychiatric disorders into adulthood. Intervening early will benefit the young people themselves but also deliver healthcare savings. The average health service cost for an adolescent who self-harms is high at £8,058 per person per year plus £7,314 per person per year social costs. Effective treatments for adolescents who repeatedly self-harm and who are at high risk of subsequent suicide are desperately needed. Previous studies of interventions for adolescent self-harm have rarely proved effective. One exception to this is a recently published study that applied Dialectical Behaviour Therapy (DBT), an established efficacious treatment originally developed for adult women with a history of repetitive self-harm in the context of borderline personality disorder. Mehlum and colleagues (2014), in a study conducted in Oslo, demonstrated efficacy for DBT with self-harming adolescents. In this study, parents were included in the psychoeducation component of the DBT treatment – a departure from the standard DBT protocol utilized with adults – previously described by Miller, Rathus, Linehan, Wetzler and Leigh (1997). Whilst this study is a welcome development in demonstrating that there is at least one effective intervention for repeated self-harm in adolescents, the particular protocol utilized restricts the flexibility of the intervention. Many adolescents with repeated self-harm may not live with their parents or may have highly conflicted relationships with them, which would preclude their participation in DBT for adolescents as tested by Mehlum and colleagues. Studies would indicate that adolescents not living with their family and those with high levels of family conflict may be especially vulnerable to suicidal behaviour and thus it is of concern that a potentially effective intervention would be denied them by insisting on parental participation or a particular form of parental participation. In addition, a key task of adolescence is to individuate from parents with peers as an important source of support for this process. The psychoeducation group component of DBT offers a unique opportunity for peer support in problem solving that may be inhibited for some adolescents in the presence of their parents. We, therefore, propose to further refine and test an alternative family and carer intervention to deliver alongside DBT that will preserve the benefits of involving parents in the treatment, whilst increasing flexibility by offering support to carers other than parents, and maintain the benefit of an adolescent only psycho-educational group for skills training. DBT was originally developed to treat women with a history of repetitive self-harm in the context of Borderline Personality Disorder (BPD). DBT is one of the most well-established treatments for this client group as indicated in a recent Cochrane Review (Stoffers et al 2013) and is also recommended by NICE (NCCMH, 2009). Following on from its promise in addressing repeated self-harm many researchers and clinicians adapted and evaluated the impact of DBT in treating adolescents with a history of self-harming (Woodberry Popenoe, 2008). A recent meta-analysis of 19 RCTs of interventions for self-harm in adolescents has in fact indicated that DBT is the most promising intervention for this population (Ougrin, Tranah, Stahl, Moran Asarnow, 2015). Linehan's biosocial model of BPD conceptualises self-harming and suicidal behaviour as the result of emotion dysregulation. Emotion dysregulation refers to the inability to regulate emotions coupled with high emotional vulnerability. This means that the emotionally dysregulated individual

is sensitive to emotional stimuli, experiences emotions intensely and for longer than would normally be the case. Emotion dysregulation is described by Linehan (1993) as the result of biological disposition, environmental context and the transaction between the two. Part of DBT involves providing skills for emotional modulation, however, young people are often still living in an environmental context which may continually precipitate and / or reinforce emotional dysregulation. Unlike adults, young people have little control over their environment, and studies have shown that addressing parents in family-centred intervention can bring about benefits for the whole family unit, including decreasing parental depressive symptomatology (Huey et al. 2004; Woodberry Popenoe, 2008). Furthermore, involving the family unit is consistent with the DBT approach, as an attempt to reduce environmental pressures on the young person. Recently, attempts have been made at providing family interventions alongside DBT for adolescents, however no family therapy model has yet been delineated for this group of young people (Miller, Glinski, Woodberry, Mitchell Indik, 2002). Miller et al. (2002) have delineated what a potential theoretical synthesis between DBT and family therapy (FT) might look like. They indicate that the "dialectical" philosophy, which views reality as an interrelated system in continuous change is compatible with a systems perspective which views family life as composed of multiple stories and views of each family member. According to Miller et al. a DBT informed family therapy approach would take a compassionate and non-judgemental stance towards parents' experiences, validating the pain and guilt that families with problematic adolescents might be experiencing and labelling behaviours as problematic rather than families. Such an approach would ideally intervene by reducing family interactions that contribute to adolescent life-threatening behaviour, reduce parental behaviour that interferes with treatment, reduce family interactions that interfere with the families' quality of life and increase families' behavioural skills in identifying triggers and potential solutions to crisis situations. Family Domains Therapy (FDT) was outlined by Hill, Fonagy, Safier and Sargent in 2003. It proposes a model of how problematic family interactions are constructed which allows families to reflect on how each family member expresses their needs and goes about getting their needs met. FDT highlights how there needs to be a shared understanding within a family in order for communication and actions to make sense to every family member. In other words, the family needs to be able to communicate about what their interaction is about. The experience of invalidation occurs when there is a misunderstanding between the child and the adult over what the nature of the interaction is. This misunderstanding can occur either due to a failure of the parent to understand the child's needs, or due to a confused or mixed expression of needs by the child. FDT therefore sees the experience of invalidation as emerging in interaction and takes a compassionate and non-judgemental stance towards all family members. According to FDT a "domain" is the combination of a child expressing his or her needs and the parent's response (Child's need + Parent's response = Domain). When children signal their needs clearly, and parents respond in ways that address them, the domain is referred to as being clear and matched: the parents' response matches the child's need. When domains are clear and matched, parents and children understand what is going on, and where there are problems, they know how they are to be addressed. When domains are unclear or unmatched, for example if the child is not signalling his or her needs clearly there can be misunderstandings about what is going on, and parents and children can feel angry, hurt or upset. FDT highlights four domains of interaction between parent and child based on the kind of needs the child can express and the parents' response. Three domains (attachment, safety and discipline) involve interactions that require a response from the parents; attachment involves acts of comforting, safety involves acts of protection and discipline involves acts of boundary setting and containment, in these three domains parental action is required in order to regulate the child's emotion. The fourth domain, exploration, involves an interaction which does not require parental action but interested curiosity, this kind of interaction increases shared knowledge and can occur only in a state of emotional regulation. FDT provides psychoeducation to parents regarding the impact of parenting emotionally vulnerable children and the emotional and behavioural changes that can be expected in adolescents; it informs parents of the domains approach and how this can help communication and increase parental reflective skills and capacity to identify the needs of the young person and respond coherently and consistently to those expressed needs. It helps parents manage the dialectics of safety versus attachment, safety versus discipline, attachment versus exploration, etc. FDT meets all the requirements that Miller et al (2002) have outlined as necessary to DBT informed family therapy intervention. It also addresses problems that parents of self-harming and suicidal adolescents have identified as areas

they need support in: communication and family relationships (Byrne et al., 2008). Overall there appears to be a clear need for the development of a family therapy model consistent with the DBT approach that supports parents/carers of self-harming young people to create an environment that can accommodate the young person's emotional vulnerability and to establish whether adding family interventions to DBT augments its effectiveness. This study will assess the acceptability of Family Domains Therapy as a potential family therapy model to be used to support the parents/carers of self-harming young people alongside DBT; it will also address the practicalities of evaluating the DBT Programmes across North Wales. Background Self-harm includes any act of intentional self-poisoning or self-injury regardless of motivation and, therefore, includes acts with suicidal intent and those without. Self-harm in adolescence is a major public health problem. The behaviour is highly prevalent (occurring in about 10% of adolescents), often repeated and is the strongest predictor of subsequent suicide. Self-harm exacts a distressing toll on young people and their families and is expensive in terms of health and social costs. Young people with repetitive self-harm often fail to achieve in education and go on to have persistent mental health problems. Suicide is the second most common cause of death in adolescence (Patton et al., 2009). Increased severity of self-harm is associated with higher levels of depression, anxiety and impulsivity (Madge et al., 2011), and patients who escalate the severity of their self-harm are at high risk of completed suicide (Carter, Reith, Whyte McPherson, 2005). Strangulation and attempted hanging in adolescents have increased, both of which are strongly associated with completed suicide (Runeson, Tidemalm, Dahlin, Lichtenstein Langstrom, 2010). 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self-harm in adolescents has in fact indicated that DBT is the most promising intervention for this population (Ougrin, Tranah, Stahl, Moran Asarnow, 2015). Linehan's biosocial model of BPD conceptualises self-harming and suicidal behaviour as the result of emotion dysregulation. Emotion dysregulation refers to the inability to regulate emotions coupled with high emotional vulnerability. This means that the emotionally dysregulated individual is sensitive to emotional stimuli, experiences emotions intensely and for longer than would normally be the case. Emotion dysregulation is described by Linehan (1993) as the result of biological disposition, environmental context and the transaction between the two. Part of DBT involves providing skills for emotional modulation, however, young people are often still living in an environmental context which may continually precipitate and / or reinforce emotional dysregulation. 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They indicate that the "dialectical" philosophy, which views reality as an interrelated system in continuous change is compatible with a systems perspective which views family life as composed of multiple stories and views of each family member. According to Miller et al. a DBT informed family therapy approach would take a compassionate and non-judgemental stance towards parents' experiences, validating the pain and guilt that families with problematic adolescents might be experiencing and labelling behaviours as problematic rather than families. Such an approach would ideally intervene by reducing family interactions that contribute to adolescent life-threatening behaviour, reduce parental behaviour that interferes with treatment, reduce family interactions that interfere with the families' quality of life and increase families' behavioural skills in identifying triggers and potential solutions to crisis situations. 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FDT provides psychoeducation to parents regarding the impact of parenting emotionally vulnerable children and the emotional and behavioural changes that can be expected in adolescents; it informs parents of the domains approach and how this can help communication and increase parental reflective skills and capacity to identify the needs of the

young person and respond coherently and consistently to those expressed needs. It helps parents manage the dialectics of safety versus attachment, safety versus discipline, attachment versus exploration, etc. FDT meets all the requirements that Miller et al (2002) have outlined as necessary to DBT informed family therapy intervention. It also addresses problems that parents of self-harming and suicidal adolescents have identified as areas they need support in: communication and family relationships (Byrne et al., 2008). Overall there appears to be a clear need for the development of a family therapy model consistent with the DBT approach that supports parents/carers of self-harming young people to create an environment that can accommodate the young person's emotional vulnerability and to establish whether adding family interventions to DBT augments its effectiveness. This study will assess the acceptability of Family Domains Therapy as a potential family therapy model to be used to support the parents/carers of self-harming young people alongside DBT; it will also address the practicalities of evaluating the DBT Programmes across North Wales.

The hypotheses

Further details: This study has two parts. PART 1 aims to assesses the feasibility, practicalities and acceptability of the recruitment and assessment procedures that would be needed to systematically assess outcome in any future RCT of DBT augmented with FDT. PART 2 aims to assesses the uptake and acceptability of Family Domains Therapy (FDT) intervention to the parents/carers of young people undergoing the DBT programme ahead of a larger fully powered RCT. In order to determine this we will assess the percentage of parents/carers who opt into the FDT intervention, the decision making process by which parents choose to opt in or out of FDT, the perceived helpfulness and benefits of the intervention, both session-by-session and at the end of the intervention. The main predictions of this study are: 1. We expect 50% of self-harming young people referred to CAMHS for DBT and their parents/carers to consent to participate in the research. 2. PART 1. We expect to be able to collect all the data necessary from 80% of young people who have agreed to participate in the study. This would be our criterion for feasibility. We expect measures to indicate a reduction in self-harming behaviour in the young people undergoing DBT, although, this is not a primary measure of outcome as this study is a feasibility pilot. 3. PART 2. We expect to be able to collect all the data necessary from 80% of parents/carers who have agreed to participate in the study. We expect that 50% of parents who agree to take part in the study will also opt into the FDT intervention. This would be our criterion for feasibility. These figures have been drafted based on local clinicians' experiences of young people and parental involvement in local Child and Adolescent Mental Health Services (CAMHS).

Participants: recruitment methods, age, gender, exclusion/inclusion criteria

Further details: Participants The study will aim to recruit 20 young people and their parents/carers from local CAMHS. The following inclusion and exclusion criteria will be adopted when recruiting participants: Inclusion Criteria: Young People: - 1) The young person meets referral criteria of the DBT Programme in his/her local CAMHS (this typically includes a minimum of 5 out of 9 criteria for Borderline Personality Disorder plus self-harming behaviour). 2) The young person is aged between 14 and 18. 3) The young person is willing and able to consent to the research. Parents/Carers:- 1) Parents and Carers of the young person who is willing and able to consent to the research. Exclusion Criteria: Young People: - 1) Intellectual Disability. 2) Acute Psychosis. 3) Lack of capacity to consent. Parents/Carers:- 1) Intellectual Disability. 2) Acute Psychosis. 3) Lack of capacity to consent. Recruitment Young people and their parents/carers who fulfil the inclusion criteria will be identified by DBT clinicians across North Wales during their routine discussion of referrals to the DBT Programme. These perspective participants will be approached by their assigned DBT clinician during their routine initial appointment to introduce the DBT intervention. During this meeting the young person and their parents/carers will receive a brief introduction to the study and its aims, and consent to meet with the research officer, Victoria Garvey, to gain more information about the study will be sought. If they consent they will be asked to sign a consent form, highlighting that they have consented to be contacted by the research officer. Families and young people will be given an information sheet, with details of the study. The research officer will contact the parents/carers and young people who have consented to be contacted no sooner than 24 hours after their initial meeting with the DBT clinician and will arrange to meet parents/carers

and young people, together or separately as they prefer. During these meeting with the research officer, the research officer will clarify the details of the study, its aims and objectives and what is required from the participants and what the benefits and possible drawbacks for the participants might be. The parents/carers will be offered the possibility of opting into a FDT intervention and the nature of the intervention will be described and information sheets will be available should the young person or the parents/carers have misplaced those initially provided. The research officer will also explain how to contact the FDT team should parents/carers decide to take part in this intervention. Consent to participate in the study will be sought. Parents/carers will be asked to read and sign two consent forms, one to consent to being participants and one to consent to the young person's participation in the study. Young people will be provided with an assent form. Should young people or their parents/carers be undecided as to whether they wish to participate, they will be given up to 24h following the meeting with the research officer to decide. Consent will need to be obtained from both the young person and their parents/carers in order for them both to be enrolled in the research. If consent is obtained, the research officer will send a letter to the participant's GP to inform them of the participants involvement in the research project. Meanwhile, the research assistant, to be appointed, will schedule an appointment with the young person for the collection of the quantitative data and a separate appointment with the parents/carers in which initial data will be collected.

Research design

Further details: Study Aims and Predictions This study has two parts. PART 1 aims to assesses the feasibility, practicalities and acceptability of the recruitment and assessment procedures that would be needed to systematically assess outcome in any future RCT of DBT augmented with FDT. PART 2 aims to assesses the uptake and acceptability of Family Domains Therapy (FDT) intervention to the parents/carers of young people undergoing the DBT programme ahead of a larger fully powered RCT. In order to determine this we will assess the percentage of parents/carers who opt into the FDT intervention, the decision making process by which parents choose to opt in or out of FDT, the perceived helpfulness and benefits of the intervention, both session-by-session and at the end of the intervention. The main predictions of this study are: 1. We expect 50% of self-harming young people referred to CAMHS for DBT and their parents/carers to consent to participate in the research. 2. PART 1. We expect to be able to collect all the data necessary from 80% of young people who have agreed to participate in the study. This would be our criterion for feasibility. We expect measures to indicate a reduction in self-harming behaviour in the young people undergoing DBT, although, this is not a primary measure of outcome as this study is a feasibility pilot. 3. PART 2. We expect to be able to collect all the data necessary from 80% of parents/carers who have agreed to participate in the study. We expect that 50% of parents who agree to take part in the study will also opt into the FDT intervention. This would be our criterion for feasibility. These figures have been drafted based on local clinicians' experiences of young people and parental involvement in local Child and Adolescent Mental Health Services (CAMHS). Methodology Design PART 1. This part of the study answers the question: Can data evaluating progress in treatment be systematically collected from young people in North Wales DBT programmes? This part of the study uses a descriptive methodology involving a single group design, consisting of young people aged 14 to 18 who have been referred to DBT Programmes across North Wales. This part of the study will audit the process, feasibility and acceptability of recruiting young people to the study and collecting pre-post treatment data from questionnaires and semi-structured interviews. The data collected will concern potential outcomes, mediators and predictors of outcomes for young people undergoing DBT. PART 2. This part of the study answers four questions: 1. How many parents/carers of young people undergoing DBT choose to take up Family Domains Therapy (FDT)? 2. Can we collect from parents/carers the data necessary to evaluate FDT? 3. How do parents/carers make the decision to opt in or out of FDT? 4. What do parents/carers find helpful about FDT? This part of the study uses a mixed-methodology involving a single group design, consisting of the parents/carers of the young people referred for DBT. Quantitative data will include the percentage of parents who opt into FDT and percentage of parents/carers who complete all pre- and post-treatment measures. Qualitative data will be collected to investigate the decision-making process by which parents choose to opt in or out of FDT, and the perceived helpfulness and benefits of the intervention. This data will include a

semi-structured interview, session-by-session qualitative feedback forms, and video-recordings of FDT sessions. Participants The study will aim to recruit 20 young people and their parents/carers from local CAMHS. The following inclusion and exclusion criteria will be adopted when recruiting participants: Inclusion Criteria: Young People: - 1) The young person meets referral criteria of the DBT Programme in his/her local CAMHS (this typically includes a minimum of 5 out of 9 criteria for Borderline Personality Disorder plus self-harming behaviour). 2) The young person is aged between 14 and 18. 3) The young person is willing and able to consent to the research. Parents/Carers:- 1) Parents and Carers of the young person who is willing and able to consent to the research. Exclusion Criteria: Young People: - 1) Intellectual Disability. 2) Acute Psychosis. 3) Lack of capacity to consent. Parents/Carers:- 1) Intellectual Disability. 2) Acute Psychosis. 3) Lack of capacity to consent. Recruitment Young people and their parents/carers who fulfil the inclusion criteria will be identified by DBT clinicians across North Wales during their routine discussion of referrals to the DBT Programme. These perspective participants will be approached by their assigned DBT clinician during their routine initial appointment to introduce the DBT intervention. During this meeting the young person and their parents/carers will receive a brief introduction to the study and its aims, and consent to meet with the research officer, Victoria Garvey, to gain more information about the study will be sought. If they consent they will be asked to sign a consent form, highlighting that they have consented to be contacted by the research officer. Families and young people will be given an information sheet, with details of the study. The research officer will contact the parents/carers and young people who have consented to be contacted no sooner than 24 hours after their initial meeting with the DBT clinician and will arrange to meet parents/carers and young people, together or separately as they prefer. During these meetings with the research officer, the research officer will clarify the details of the study, its aims and objectives and what is required from the participants and what the benefits and possible drawbacks for the participants might be. The parents/carers will be offered the possibility of opting into a FDT intervention and the nature of the intervention will be described and information sheets will be available should the young person or the parents/carers have misplaced those initially provided. The research officer will also explain how to contact the FDT team should parents/carers decide to take part in this intervention. Consent to participate in the study will be sought. Parents/carers will be asked to read and sign two consent forms, one to consent to being participants and one to consent to the young person's participation in the study. Young people will be provided with an assent form. Should young people or their parents/carers be undecided as to whether they wish to participate, they will be given up to 24h following the meeting with the research officer to decide. Consent will need to be obtained from both the young person and their parents/carers in order for them both to be enrolled in the research. If consent is obtained, the research officer will send a letter to the participant's GP to inform them of the participant's involvement in the research project. Meanwhile, the research assistant, to be appointed, will schedule an appointment with the young person for the collection of the quantitative data and a separate appointment with the parents/carers in which initial data will be collected. Study Settings This study will take place in community CAMHS settings across Betsi Cadwaladr University Health Board. PART 1. All data from young people will be collected in clinical rooms at the local CAMHS setting by a dedicated psychology assistant employed by BCUHB and trained in the study methodology and in the assessment tools and supervised by Dr Swales. PART 2. Quantitative data and semi-structured interview data will either be collected at the family home or at their local CAMH service depending on parents' preference by a key researcher (Psychology Assistant or Trainee Clinical Psychologist) employed by BCUHB and trained in the assessment tools. Session-by-session qualitative rating forms and therapy session video-recordings will be collected by the BCUHB employed family therapists delivering FDT on CAMHS premises. Safeguarding and Risk Management Participants will be informed that should they disclose information about themselves or others being at serious risk of harm during any of the research procedures, the research team member will have to communicate that information to the young person's assigned DBT clinician and local service safeguarding procedures will be followed as stated on the participant consent forms. There is a potential risk for researchers collecting data in family homes. Researchers going to family homes will follow local health board and service lone worker policies to ensure they log their absences from the office, and their research supervisor knows where they are, and both researcher and supervisor know emergency procedures. Parents/Carers who take part in this research will be known to services, where there are pre-existing concerns about risk to the researcher home visits for data collection will not be offered.

Ethical Considerations on Participant Information and Anonymity Participants will be provided with an information sheet explaining the aims of the study. The information sheet will also contain contact details of the research team for any future questions they may have and provide contacts for REC members, should the participants wish to raise concerns about the conduct of the study. Participants will also be informed that the data they provide will remain anonymous and cannot be traced to their identity. The information sheet will also explain their right to withdraw at any time. Following NHS ethics guidelines, participants will also be asked to read and sign consent and assent forms. Standard procedures to ensure the anonymity and the confidentiality of the data will be adhered to. All participants will be made aware that they may withdraw from the study at any point even after it has been completed. Participants will also be informed that their decision to withdraw at any stage of the study will not affect in any way the treatment they are receiving at their local CAMHS. Young people will all access the DBT programme as they would do ordinarily in CAMHS whether they choose to take part in the research project or not. Parents/Carers will only be able to access Family Domain Therapy (FDT) if they opt into the research, however, they will still be able to access non-specified family therapy (treatment as usual) from the same family therapists that are delivering FDT should they refuse consent to participate in this research project. Materials and Procedure The study consists of two parts; PART 1 addresses the feasibility and acceptability of collecting data necessary for the evaluation of Dialectical Behaviour Therapy (DBT) from young people referred to the DBT programme. This data will be collected pre-post the young person's treatment. PART 2 addresses the feasibility and acceptability of offering Family Domains Therapy (FDT), collecting the data necessary for the evaluation of FDT and exploring how parents make the choice to opt into FDT or not, and what they find helpful about it. PART 1: YOUNG PEOPLE Once the young person's assent to participate in the research and their parent/carer's consent has been gained, the research assistant, will arrange a meeting with the young person to complete the following assessment questionnaires and semi-structured interviews prior to the commencement of the DBT programme: a. Borderline Symptom List-23 (Bohus et al., 2009) The Borderline Symptom List – 23 (BSL-23) was developed as a self-rating instrument to specifically quantify borderline-typical symptomatology. The items are based on the criteria of the DSM-IV, the Diagnostic Interview for Borderline Personality Disorder – revised version, the opinions of clinical expert and borderline patients. The BSL is composed of 23 items that are rated using a 5-point scale (0=not at all, 4=very strong). The BSL has been used in recent RCT of DBT for self-harming adolescents (Mehlum et al., 2014), therefore this measure was included in this study as a potential DBT outcome measure. b. DBT Ways of Coping Check-list (Neacsiu, Rizvi, Vitaliano, Lynch Linehan, 2010) The DBT Ways of Coping Check-list (DBT-WCCL) is a measure of the participant coping skills. It is a 59-item self-report scale. Each item is rated on a 4-point scale (0=never used, 3=regularly used). The DBT-WCCL is composed of two sub-scales the DBT Skills Subscale which assesses coping via the DBT skills and the Dysfunctional Coping Sub-scale (DCS) which assesses coping via dysfunctional means. It is a standard DBT outcome measure as it can successfully discriminate participants who receive skills training from those who don't. Skills training is a crucial mode of treatment in DBT and a significant moderator of symptom reduction (Neasciu et al, 2010). c. Lifetime Parasuicide Count (Comtois Linehan, 1999) The Lifetime Para-suicide Count (LPC) is a semi-structured interview used to measure lifetime history of self-injurious behaviour grouped by method, intent to die, and level of medical treatment. The interview is preceded by an introduction and a definition of para-suicide. The LPC is a standard assessment measure in DBT which is routinely used with adolescent outpatients and has been recently used as assessment tool in an RCT of DBT for self-harming adolescents (Miller, Rathus Linehan, 2007; Mehlum et al., 2014). d. Zanarini Rating Scale for Borderline Personality Disorder (Zanarini, 2003) The Zanarini Rating Scale for Boderline Personality Disorder (ZAN-BPD) is a brief clinician-administered interview to assess severity and change in BPD symptomatology. It has been included in this study as a potential outcome measure of DBT. The completion of the above-mentioned measures will require approximately one to one and a half hours and might be conducted over two meetings if necessary. On all occasions the young person's assigned DBT clinician will be available to the young person following the data collection to address any distress caused by the completion of questionnaires or the semi-structured interview. The research assistant will also remind the young person that they can ask to terminate the interview at any time without having to give an explanation. Following this initial data collection parents/carers will be invited to join their young person for a problem-solving assessment. In order to assess problem-solving the research assistant will conduct the Means

Ends Problem-Solving Test (Platt Spivak, 1975) with the young person in the presence of their parents/carers. The Means Ends Problem-Solving Test consists of 5 everyday problem-solving challenges. The young person will be asked how they might go about solving the problem and they will be oriented to discuss / seek advice from their parent/carers if they wish to do so. The interaction will be videotaped to capture their answers and the interaction with the parent. Problem-solving skills are known to be adversely affected in those who self-harm (Nock Mendes, 2008), and for this reason DBT has a specific focus on skills training (Linehan, 1993). Thus, assessing problem-solving is a way to measure potential outcomes of DBT. Additionally, the presence of the parent/carer will allow assessment of whether and in what way the young person requests help from their parent/carer, the quality of the interaction and the level of helpfulness, all of which are potential outcomes and potential predictors of outcomes of Family Domains Therapy. After these procedures the young person will commence the DBT Programme. When the young person comes to the end of their DBT treatment, the research assistant will arrange to meet with the young person, and measures a, b, c d and the Means-Ends Problem-Solving test will be repeated. PART 2A: PARENTS/CARERS Once the parents/carers' consent to participate in the research and their consent for the young person to participate in the research is gained (Appendices 18 19), the research assistant will arrange a meeting with the parents/carers to complete the following assessment questionnaires: a. General Health Questionnaire (Goldberg, 1978) The General Health Questionnaire (GHQ) was developed as a screening instrument to identify psychological distress amongst adults in primary care settings. It is comprised of 60 self-report items on a 4-point scale (0=not at all, 3=more than usual). Research shows that parents/carers of children with behavioural problems often experience significant stress (Mouton Tuma, 1988; Mash Johnston, 1983; Patterson, 1982). Parent/carer mental health has been shown to be a barrier to parent/carer engagement in children's treatment (Morrissey-Kane Prinz, 1999). The GHQ is a non-specific, broad screening tool which was included in this study as it might capture changes in various aspects of parental mental health throughout their young person's treatment and their own engagement in FDT, should they choose to engage with it. b. Beck Depression Inventory - II (Beck, Steer Brown, 1996) The Beck Depression Inventory-II (BDI-II) is the most widely used tool to screen for depression in adult populations. It consists of 21 items to assess the intensity of depression in clinical and normal populations. Each item is a list of four statements arranged in increasing severity about a particular symptom of depression from which the participant must choose the one that best describes the way s/he has been feeling in the past week. The manual provides clinical cut-offs. Research suggests that parents/carers of children with behavioural problems often experience depression (Griest, Wells Forehand, 1979; Griest Wells, 1983), that depression can be a barrier to parental engagement and a predictor of parent/carer drop out (Morrissey-Kane Prinz, 1999; Woodberry and Popenoe, 2008). The BDI-II was included in this study as measuring level of parent/carer depression might be beneficial to predict parental engagement and as a potential outcome measure of the young person's treatment or parents/carers' engagement in FDT. c. SCORE-15 (Stratton et al., 2013) The SCORE-15 Index of Family Functioning and Change is a validated self-report outcome measure designed to be sensitive to the kind of changes in family relationships that family therapists see as indications of useful therapeutic change. It is composed of 15 items and six indicators, three of them qualitative. The SCORE-15 was included in this study as potential outcome measure of FDT. d. Appendix 9 - Parent Child Emotions and Behaviours Questionnaire The Parent Child Emotions and Behaviours Questionnaire (PCEBQ) is a brief 10 item self-report questionnaire which asks parents/carers to rate their responses on a 5-point scale (0=never, 4=most of the time). The questionnaire was designed as an assessment and outcome tool for Family Domains Therapy (FDT) and it explores the way the parent/carer responds to the child, the parent/carer's understanding of the child's needs and the parent/carer's awareness of the way in which they communicate with their child. e. Parent Orientation Questionnaire The Parent Orientation Questionnaire is a brief 11 item self-report questionnaire that was designed for this study. There are 10 quantitative items which request the parent/carer to define the extent of the child's difficulties, their perceived role in the child's recovery, parental readiness to receive help and advice and parental concern on a continuous scale (far left=not at all, far right= a lot). It also includes one open question which explores parental attributions of their child's difficulties. This scale has been devised as a potential assessment tool for Family Domains Therapy (FDT). Each questionnaire should take no longer than five minutes to complete, overall completion of all questionnaires will require approximately 30 minutes. For each

questionnaire participants will be informed that they should only proceed so long as comfortable, that they can stop the meeting at any point and that they do not have to answer every question if they do not wish to do so. Following the completion of the questionnaires, initial qualitative data will be collected. The research assistant will collect a Five Minute Speech Sample (Calam Peters, 2006) of the parents describing their young person, which will be analysed to assess expressed emotion towards the young person. The same procedure will be followed at the end of the young person's treatment, with the addition of a semi-structured interview to explore how the parents/carers decided whether to opt into the FDT intervention or not, and if they have what benefits they ascribe to the treatment. The semi-structured interview should take approximately 45 minutes, bringing the end of treatment data collection meeting to approximately one hour and 15 minutes. This semi-structured interview was constructed using questions from the Change Interview (Elliott, 2008) a qualitative tool to explore post-treatment changes and from the literature on barriers to engagement in therapy (Kazdin, Holland, Crowley, Breton, 1997) PART 2B: PARENTS/CARERS WHO OPT FOR FAMILY DOMAIN THERAPY. In order to explore which specific aspects of Family Domains Therapy parents/carers find useful the following qualitative data will be collected from the parents/carers who choose to undergo Family Domains Therapy. All therapy sessions will be video-recorded as this is a novel intervention. The video-recordings will be used to assist in describing the intervention in more detail for any subsequent research study, for further detailing of the Family Domains Therapy manual and in order to explore which aspects of FDT parents/carers find helpful or hindering. In order to accomplish the latter task, at the end of each therapy session the parents/carers will be asked to complete a Helpful Aspects of Therapy Form (HAT; Llewelyn, 1988) to indicate what aspects of that specific session they found helpful or unhelpful. This form should take approximately 5 minutes to complete. The use of session-by-session rating scales is routine within CAMHS settings, and associated with better outcomes in therapy. The HAT form is a qualitative post-session self-report questionnaire which uses open-ended questions to help clients write down their experiences of helpful and hindering therapy events, rate their helpfulness or unhelpfulness and indicate where in the therapy session they occurred and why they believe such events were helpful or hindering. It is a simple and efficient means of soliciting information from clients about their perceptions of key change processes in therapy. The HAT form is considered a less-intrusive and naturalistic way of collecting data, it becomes a routine part of the participants' overall therapy experiences and appears to help clients process their therapy more effectively (Elliott, 2012). The HAT's open-ended format generates qualitative data of sufficient detail and focus as to lend itself to various uses, including identification of significant events, descriptive and interpretive forms of qualitative data analysis and even quantitative content analysis (Elliott, 2012). When parent/carers near the end of their FDT treatment, the trainee clinical psychologist, Stefania Pethica, will collect all completed HAT forms and identify on video-recordings of therapy sessions the specific interactions that parents/carers have highlighted as helpful. Due to the novel nature of Family Domains Therapy, it is essential to explore what specific aspects of the therapy parents/carers find helpful in order to isolate what the change ingredients of the therapy might be, in view of developing the treatment to undergo a fully powered randomised controlled trial. Final Debriefing Following the data analysis a summary of main findings will be sent by post to parents/carers and young people and their views (agreement/disagreement) on such findings will be sought and integrated in the write-up of the study. Data Analysis PART1. This part of the study regards the feasibility and acceptability of assessing the outcomes, mediators and predictors of outcomes of DBT in North Wales. Therefore the process of recruitment, ease and acceptability of data collection is of primary interest. Data analysis will include audit of the number of young people and their parents/carers recruited and the number of participants completing all procedures of data collection. PART2. This part of the study regards the feasibility and acceptability of offering Family Domains Therapy to the parents/carers of the young people undergoing the DBT programme as well as the feasibility and acceptability of assessing the outcomes, mediators and predictors of outcomes of FDT. Of primary interest is the process of recruitment, ease and acceptability of data collection. Data analysis will include audit of number of parent/carers who opt into FDT and number of parents/carers completing all procedures of data collection. Due to the novel nature of Family Domains Therapy (FDT), this part of the research also includes the collection of qualitative data to explore how parents make the decision to opt into FDT or not and what they find helpful about FDT. Qualitative interview data collected in the final interview with both parents who have opted into FDT and those who haven't will employ a

thematic analysis. Thematic analysis involves the transcription of interviews and the repeated reading of the material in order to highlight sub-themes that emerge from the text. Sub-themes are then collected into larger thematic categories that might be recurrent across several interviews with different individuals. This analysis would allow the understanding of barriers and incentives to engaging in FDT, the acceptability and feasibility of offering FDT according to parents/carers, and for those who participated in FDT the post-treatment benefits they can identify. All of this data will be essential for the future planning of a fully powered randomized controlled trial (RCT) of FDT as it will allow the prediction of potential barriers and incentives to engagement as well as the selection of outcome measures that tap into the outcomes identified by the participants. Qualitative session-by-session data collected with the Helpful Aspects of Therapy form (HAT) will be used to guide the analysis of helpful processes that occur during the therapy itself. In the HAT form participants highlight what they have found helpful in a specific therapy session, the collection of this data allows the understanding of the immediate effects (micro-outcomes) of important moments in psychotherapy. This data will be used to conduct a quantitative content analysis of what aspects of therapy participants found helpful, it will also indicate in which therapy sessions helpful events occurred. The Trainee Clinical Psychologist, Stefania Pethica, will use the HAT form to identify the helpful event within the therapy session video recording and conduct a dialogical sequence analysis of the helpful event (Linell, 1998; Leiman, 2012). Dialogical sequence analysis involves taking topical episodes in the therapeutic conversation as focus for analysis and transcribing them for analysis. The analysis highlights aspects of the interaction, and what participants are doing in the conversation, how they position themselves towards the speaker and towards the problem being discussed. Investigating which processes parents/carers find helpful may lead to the further understanding of how the family psychotherapy process helps families make sense of their experiences and generate helpful solutions to their difficulties. Dissemination DBT team members meet weekly and any information requiring immediate dissemination can be fed back to participants through this route. The research assistant devoted to the project will also take responsibility for contacting participants promptly with any relevant information. The findings of this study will be used in a grant application to systematically evaluate whether FDT can augment the outcomes of DBT. The findings of this study will also be used for a doctoral thesis by one of the key researchers, Trainee Clinical Psychologist, Stefania Pethica. Additionally, the results of this study may be published in peer-reviewed journals and presented at conferences. Participants will be given contact details for requesting a copy of the results if they so wish.

Procedures employed

Further details: Materials and Procedure The study consists of two parts; PART 1 addresses the feasibility and acceptability of collecting data necessary for the evaluation of Dialectical Behaviour Therapy (DBT) from young people referred to the DBT programme. This data will be collected pre-post the young person's treatment. PART 2 addresses the feasibility and acceptability of offering Family Domains Therapy (FDT), collecting the data necessary for the evaluation of FDT and exploring how parents make the choice to opt into FDT or not, and what they find helpful about it. PART 1: YOUNG PEOPLE Once the young person's assent to participate in the research and their parent/carer's consent has been gained, the research assistant, will arrange a meeting with the young person to complete the following assessment questionnaires and semi-structured interviews prior to the commencement of the DBT programme: a. Borderline Symptom List-23 (Bohus et al., 2009) The Borderline Symptom List – 23 (BSL-23) was developed as a self-rating instrument to specifically quantify borderline-typical symptomatology. The items are based on the criteria of the DSM-IV, the Diagnostic Interview for Borderline Personality Disorder – revised version, the opinions of clinical expert and borderline patients. The BSL is composed of 23 items that are rated using a 5-point scale (0=not at all, 4=very strong). The BSL has been used in recent RCT of DBT for self-harming adolescents (Mehlum et al., 2014), therefore this measure was included in this study as potential DBT outcome measure. b. DBT Ways of Coping Checklist (Neacsiu, Rizvi, Vitaliano, Lynch Linehan, 2010) The DBT Ways of Coping Checklist (DBT-WCCL) is a measure of the participant coping skills. It is a 59-item self-report scale. Each item is rated on a 4 point scale (0=never used, 3=regularly used). The DBT-WCCL is composed of two subscales the DBT Skills Subscale which assesses coping via the DBT skills and the Dysfunctional Coping Subscale (DCS) which assesses coping via dysfunctional means. It is a standard DBT outcome

measure as it can successfully discriminate participants who receive skills training from those who don't. Skills training is a crucial mode of treatment in DBT and a significant moderator of symptom reduction (Neasciu et al, 2010). c. Lifetime Parasuicide Count (Comtois Linehan, 1999) The Lifetime Parasuicide Count (LPC) is a semi-structured interview used to measure lifetime history of self-injurious behaviour grouped by method, intent to die, and level of medical treatment. The interview is preceeded by an introduction and a definition of parasuicide. The LPC is a standard assessment measure in DBT which is routinely used with adolescent outpatients and has been recently used as assessment tool in an RCT of DBT for self-harming adolescents (Miller, Rathus Linehan, 2007; Mehlum et al., 2014). d. Zanarini Rating Scale for Borderline Personality Disorder (Zanarini, 2003) The Zanarini Rating Scale for Boderline Personality Disorder (ZAN-BPD) is a brief clinician administered interview to assess severity and change in BPD symptomatology. It has been included in this study as a potential outcome measure of DBT. The completion of the above mentioned measures will require approximately one to one and a half hours and might be conducted over two meetings if necessary. On all occasions the young person's assigned DBT clinician will be available to the young person following the data collection to address any distress caused by the completion of questionnaires or the semi-structured interview. The research assistant will also remind the young person that they can ask to terminate the interview at any time without having to give an explanation. Following this initial data collection parents / carers will be invited to join their young person for a problem-solving assessment. In order to assess problem-solving the research assistant will conduct the Means Ends Problem-Solving Test (Platt Spivak, 1975) with the young person in the presence of their parents/carers. The Means Ends Problem-Solving Test consists of 5 everyday problem-solving challenges. The young person will be asked how they might go about solving the problem and they will be oriented to discuss / seek advice from their parent/carers if they wish to do so. The interaction will be videotaped to capture their answers and the interaction with the parent. Problem-solving skills are known to be adversely affected in those who self-harm (Nock Mendes, 2008), and for this reason DBT has a specific focus on skills training (Linehan, 1993). Thus, assessing problem-solving is a way to measure potential outcomes of DBT. Additionally, the presence of the parent/carer will allow the assessment of if and how the young person requests help from their parent/carer, the quality of the interaction and the level of helpfulness, all of which are potential outcomes and potential predictors of outcomes of Family Domains Therapy. After these procedures the young person will commence the DBT Programme. When the young person comes to the end of their DBT treatment, the research assistant will arrange to meet with the young person, and measures a, b, c d and the Means-Ends Problem-Solving test will be repeated. PART 2A: PARENTS/CARERS Once the parents/carers' consent to participate in the research and their consent for the young person to participate in the research is gained, the research assistant will arrange a meeting with the parents/carers to complete the following assessment questionnaires: a. General Health Questionnaire (Goldberg, 1978) The General Health Questionnaire (GHQ) was developed as a screening instrument to identify psychological distress amongst adults in primary care settings. It is comprised of 60 self-report items on a 4-point scale (0=not at all, 3=more than usual). Research shows that parents/carers of children with behavioural problems often experience significant stress (Mouton Tuma, 1988; Mash Johnston, 1983; Patterson, 1982). Parent/carer mental health has been shown to be a barrier to parent/carer engagement in children's treatment (Morrissey-Kane Prinz, 1999). The GHQ is a non-specific, broad screening tool which was included in this study as it might capture changes in various aspects of parental mental health throughout their young person's treatment and their own engagement in FDT, should they choose to engage with it. b. Beck Depression Inventory - II (Beck, Steer Brown, 1996) The Beck Depression Inventory-II (BDI-II) is the most widely used tool to screen for depression in adult populations. It consists of 21 items to assess the intensity of depression in clinical and normal populations. Each item is a list of four statements arranged in increasing severity about a particular symptom of depression from which the participant must choose the one that best describes the way s/he has been feeling in the past week. The manual provides clinical cut-offs. Research suggests that parents/carers of children with behavioural problems often experience depression (Griest, Wells Forehand, 1979; Griest Wells, 1983), that depression can be a barrier to parental engagement and a predictor of parent/carer drop out (Morrissey-Kane Prinz, 1999; Woodberry and Popenoe, 2008). The BDI-II was included in this study as measuring level of parent/carer depression might be beneficial to predict parental engagement and as a potential outcome measure of the young person's treatment or

parents/carers' engagement in FDT. c. SCORE-15 (Stratton et al., 2013) The SCORE-15 Index of Family Functioning and Change is a validated self-report outcome measure designed to be sensitive to the kind of changes in family relationships that family therapists see as indications of useful therapeutic change. It is composed of 15 items and six indicators, three of them qualitative. The SCORE-15 was included in this study as potential outcome measure of FDT. d. Parent Child Emotions and Behaviours Questionnaire The Parent Child Emotions and Behaviours Questionnaire (PCEBQ) is a brief 10 item self-report questionnaire which asks parents/carers to rate their responses on a 5-point scale (0=never, 4=most of the time). The questionnaire was designed as an assessment and outcome tool for Family Domains Therapy (FDT) and it explores the was the parent/carer responds to the child, the parent/carer's understanding of the child's needs and the parent/carer's awareness of the way in which they communicate with their child. e. Parent Orientation Questionnaire The Parent Orientation Questionnaire is a brief 11 item self-report questionnaire that was designed for this study. There are 10 quantitative items which request the parent/carer to define the extent of the child's difficulties, their perceived role in the child's recovery, parental readiness to receive help and advice and parental concern on a continuous scale (far left=not at all, far right= a lot). It also includes one open question which explores parental attributions of their child's difficulties. This scale has been devised as a potential assessment tool for Family Domains Therapy (FDT). Each questionnaire should take no longer than five minutes to complete, overall completion of all questionnaires will require approximately 30 minutes. For each questionnaire participants will be informed that they should only proceed as they are comfortable, that they can stop the meeting at any point and that they do not have to answer every question if they do not wish to do so. Following the completion of the questionnaires, initial qualitative data will be collected. The research assistant will collect a Five Minute Speech Sample (Calam Peters, 2006) of the parents describing their young person, which will be analysed to assess expressed emotion towards the young person. The same procedure will be followed at the end of the young person's treatment, with the addition of a semi-structured interview to explore how the parents/carers decided whether to opt into the FDT intervention or not, and if they have what benefits they ascribe to the treatment. The semi-structured interview should take approximately 45 minutes, bringing the end of treatment data collection meeting to approximately one hour and 15 minutes. This semi-structured interview was constructed using questions from the Change Interview (Elliott, 2008) a qualitative tool to explore post-treatment changes and from the literature on barriers to engagement in therapy (Kazdin, Holland, Crowley, Breton, 1997) PART 2B: PARENTS/CARERS WHO OPT FOR FAMILY DOMAIN THERAPY. In order to explore which specific aspects of Family Domains Therapy parents/carers find useful the following qualitative data will be collected from the parents/carers who choose to undergo Family Domains Therapy. All therapy sessions will be video-recorded as this is a novel intervention. The video-recordings will be used to assist in describing the intervention in more detail for any subsequent research study, for further detailing of the Family Domains Therapy manual and in order to explore which aspects of FDT parents/carers find helpful or hindering. In order to accomplish the latter task, at the end of each therapy session the parents/carers will be asked to complete a Helpful Aspects of Therapy Form (HAT; Llewelyn, 1988) to indicate what aspects of that specific session they found helpful or unhelpful. This form should take approximately 5 minutes to complete. The use of session-by-session rating scales is routine within CAMHS settings, and associated with better outcomes in therapy. The HAT form is a qualitative post-session self-report questionnaire which uses open-ended questions to help clients write down their experiences of helpful and hindering therapy events, rate their helpfulness or unhelpfulness and indicate where in the therapy session they occurred and why they believe such events were helpful or hindering. It is a simple and efficient means of soliciting information from clients about their perceptions of key change processes in therapy. The HAT form is considered a less-intrusive and naturalistic way of collecting data, it becomes a routine part of the participants' overall therapy experiences and appears to help clients process their therapy more effectively (Elliott, 2012). The HAT's open-ended format generates qualitative data of sufficient detail and focus that it lends itself to various uses, including identification of significant events, descriptive and interpretive forms of qualitative data analysis and even quantitative content analysis (Elliott, 2012). When parent/carers near the end of their FDT treatment, the trainee clinical psychologist, Stephanie Parks, will collect all completed HAT forms and identify on video-recordings of therapy sessions the specific interactions that parents/carers have highlighted as helpful. Due to the novel nature of Family Domains Therapy, it is essential to

explore what specific aspects of the therapy parents/carers find helpful in order to isolate what the change ingredients of the therapy might be, in view of developing the treatment to undergo a fully powered randomised controlled trial.

Measures employed
Further details: Young Person Measures - Research Assistant BORDERLINE SYMPTOM CHECKLIST-23 (Bohus et al., 2009) DBT WAYS OF COPING CHECKLIST (Neacsiu, Rizvi, Vitaliano, Lynch Linehan, 2010) LIFETIME PARA-SUICIDE COUNT (Comtois Linehan, 1999) ZANARINI RATING SCALE FOR BORDERLINE PERSONALITY DISORDER (Zanarini, 2003) MEANS END PROBLEM SOLVING TEST (Platt Spivak, 1975) Parent/Carer Measures - Research Assistant GENERAL HEALTH QUESTIONNAIRE (Goldberg, 1978) BECK DEPRESSION INVENTORY – II (Beck, Steer Brown, 1996) SCORE-15 (Stratton et al., 2010) PARENT CHILD EMOTIONS AND BEHAVIOURS QUESTIONNAIRE PARENT ORIENTATION QUESTIONNAIRE FIVE MINUTE SPEECH SAMPLE MANUAL (Calam Peters, 2006) Parent/Carers - This measure will be handed out at the end of each therapy session by the BCUHB employed family therapist HELPFUL ASPECTS OF THERAPY FORM (Llewelyn, 1988)

Qualifications of the investigators to use the measures (Where working with children or vulnerable adults, please include information on investigators' CRB disclosures here.)
Further details: Research Assistant - to be employed - Psychology graduate supervised by Dr Swales Research Officer - Victoria Garvey Bsc Applied Psychology PgCert Public Health Training in: Communicating with research participants – Nov 2014 Good Clinical Practice – July 2014 Trainee Clinical Psychologist - Stefania Parks Currently in the 2nd year of the NWCPP PgDip in Applied Systemic Theory Bsc Personality Psychology and Interpersonal Relationships

Venue for investigation
Further details: This study will take place in community CAMHS settings across Betsi Cadwaladr University Health Board. PART 1. All data from young people will be collected in clinical rooms at the local CAMHS setting by a dedicated psychology assistant employed by BCUHB and trained in the study methodology and in the assessment tools and supervised by Dr Swales. PART 2. Quantitative data and semi-structured interview data will either be collected at the family home or at their local CAMH service depending on parents' preference by a key researcher (Psychology Assistant or Trainee Clinical Psychologist) employed by BCUHB and trained in the assessment tools. Session-by-session qualitative rating forms and therapy session video-recordings will be collected by the BCUHB employed family therapists delivering FDT on CAMHS premises.

Estimated start date and duration of the study (N.B. If you know that the research is likely to continue for more than three years, please indicate this here).
Further details: Start date Jan 2016 end date March 2017

Data analysis
Further details: Data Analysis PART1. This part of the study regards the feasibility and acceptability of assessing the outcomes, mediators and predictors of outcomes of DBT in North Wales. Therefore the process of recruitment, ease and acceptability of data collection is of primary interest. Data analysis will include audit of number of young people and their parents/carers recruited and number of participants completing all procedures of data collection. PART2. This part of the study regards the feasibility and acceptability of offering Family Domains Therapy to the parents/carers of the young people undergoing the DBT programme as well as the feasibility and acceptability of assessing the outcomes, mediators and predictors of outcomes of FDT. Of primary interest is the process of recruitment, ease and acceptability of data collection. Data analysis will include audit of number of parent/carers who opt into FDT and number of parents/carers completing all procedures of data collection. Due to the novel nature of Family Domains Therapy (FDT), this part of the research also includes the collection of qualitative data to explore how parents make the decision to opt into FDT or not and what they find helpful about FDT. Qualitative interview data collected in the final interview with both parents who have opted into FDT and those who haven't will employ a thematic analysis. Thematic analysis involves the transcription of

interviews and the repeated reading of the material in order to highlight sub-themes that emerge from the text. Sub-themes then get collected into larger thematic categories that might be recurrent across several interviews with different individuals. This analysis would allow the understanding of barriers and incentives to engaging in FDT, the acceptability and feasibility of offering FDT according to parents/carers, and for those who participated in FDT the post-treatment benefits they can identify. All of this data will be essential for the future planning of a fully powered randomized controlled trial (RCT) of FDT as it will allow to predict potential barriers and incentives to engagement as well as measure outcomes identified by the participants. Qualitative session-by-session data collected with the Helpful Aspects of Therapy form (HAT) will be used to guide the analysis of helpful processes that occur during the therapy itself. In the HAT form participants highlight what they have found helpful in a specific therapy session, the collection of this data allows the understanding of the immediate effects (micro-outcomes) of important moments in psychotherapy. This data will be used to conduct a quantitative content analysis of what aspects of therapy participants found helpful, it will also indicate in which therapy sessions helpful events occurred. The Trainee Clinical Psychologist, Stephanie Parks, will use the HAT form to identify the helpful event within the therapy session video recording and conduct a dialogical sequence analysis of the helpful event (Linell, 1998; Leiman, 2012). Dialogical sequence analysis involves taking topical episodes in the therapeutic conversation as focus for analysis and transcribing them for analysis. The analysis highlights aspects of the interaction, and what participants are doing in the conversation, how they position themselves towards the speaker and towards the problem being discussed. Investigating which processes parents/carers find helpful might lead to the further understanding of how the family psychotherapy process helps families make sense of their experiences and generate helpful solutions to their difficulties.

Potential offence/distress to participants

Further details: 1. Young people taking part in the study will be required to complete additional questionnaires and interviews (see Methodology). This might involve discussing distressing topics. The clinicians delivering said questionnaires and interviews are all trained with working with this population and all of these additional measures are routinely used in other services. To ensure young people are supported throughout this procedure, should interviews and/or questionnaires prove distressing, every young person will have access to their CAMHS clinician following completion of additional measures. Young people will be reminded that they can drop out of the research at any point without being asked any questions. In addition, as a routine part of DBT, young people will have access to the telephone number of their assigned clinician to contact if they experience distress related to their condition or related to the research procedures throughout their treatment. 2. All young people referred for DBT and their parents/carers will be offered the opportunity to take part in the research project. Within the research project parents/carers will be offered the possibility of accessing a novel intervention: Family Domains Therapy (FDT). Parents/carers who do not opt into the research will still be able to access non-specified family interventions as currently provided by their local services. Participation in research will not affect provision of local services or what young people or parents/carers are offered (treatment as usual). Some distress might be caused to parents/carers from discussing family issues during the FDT intervention, however this would be no different to the potential for distress in other types of family intervention/therapy. The family therapists conducting the FDT intervention are all trained and supervised by the developer of FDT. FDT takes a non-judgemental and compassionate stance towards all family members. 3. A qualitative interview will be conducted with parents/carers only at the end of their involvement with FDT or of their young person's DBT treatment (if parents/carers not involved in FDT). Although discussing family matters may cause some distress commonly people find it helpful to articulate their experience and their point of view. The final interview will allow parents/carers to give their opinion on the treatment they have received and contribute to the development of a novel intervention. Parents/Carers will be informed that they can choose to stop the interview at any time.

Procedures to ensure confidentiality and data protection

Further details: All participants will be allocated an identifying code unique to them.
All experimental materials will only use this code for identification, no other details leading to identification will be reco

Codes will be stored separately from personal identifying information. All data in paper format will be held in securely locked metal filing cabinets in the office of the Chief Investigator (Dr Michaela Swales). All data in digital form (qualitative data recordings, anonymized quantitative data, anonymized qualitative data transcripts) will be held either on encrypted USB sticks or on the BCUHB secure network drive, accessed by a BCUHB laptop which will also be encrypted. All digital data will be held in password protected folders. All laptops used will be password protected, no data will be stored on computer hard drives. An audio recording device will be used to collect qualitative data and will be stored in a securely locked metal filing cabinet in the office of Dr Swales. Following each interview mp3 files of the qualitative data will be moved from the recording device to an encrypted USB stick in a password protected file and permanently deleted from the audio recording device. The same procedure will be followed for video files. Any video-recording devices employed will be property of BCUHB. Each family therapist and the research assistant will be assigned a video-recording device, these will be stored in a securely locked metal filing cabinet in their offices on BCUHB premises. Following each session video files of the qualitative data will be moved from the recording device to a password protected BCUHB computer in a password protected file and permanently deleted from the video recording device. The Trainee Clinical Psychologist will access video-files on BCUHB premises using BCUHB computers for qualitative data analysis. An anonymous ID code will be assigned to each participant and used as the only identifier in all experimental materials. The data produced by the study will only contain the anonymous identifier codes, and all work done on the data will use those codes only. The master list of personal contact details that links to the anonymous ID codes will be kept separate and securely locked away from all other materials in the office of the Chief Investigator (Dr Michaela Swales). Where direct quotes of participants will be used a pseudonym will be assigned to each participant. The research team will only have access to demographic data and the personal data that allows them to contact the participants in order to schedule appointments for interviews/data collection.
Only the research team will have access to participants' personal data during the study. Personal data will be kept securely and separate from all other research data and only used when required to fulfil the ethical obligations of the study and to contact participants to arrange appointments for data collection.
All necessary work will be carried out with anonymised data which will not be traceable to any individual personal data. Video and audio recordings will be accessed by researchers at on BCUHB premises. Data generated will be analysed by the Research Assistant and Trainee Clinical Psychologist. Anonymised data analysis will be conducted at on BCUHB premises. Digital data will be stored on encrypted USB in password protected file, and paper data will be stored in securely locked metal filing cabinet together with USB. These will be stored in the office of Research Supervisor Dr Michaela Swales. Anonymized data (such as anonymized quantiative data or anonymized qualitative transcripts) could be made accessible to Trainee Clinical Psychologists for the analysis of family functioning or to conduct Service Related Research Projects in the future. Consent for use of anonymized data in future research will be sought from participants and will be included in the consent forms.

How consent is to be obtained (see BPS Guidelines and ensure consent forms are expressed bilingually where appropriate. The University has its own Welsh translations facilities on extension 2036)

Further details: All forms will be translated. If participants give consent to meet with the research officer to gain more info about the research project, the research officer will contact the parents/carers and young people who have consented to be contacted no sooner than 24 hours after their initial meeting with the DBT clinician and will arrange to meet parents/carers and young people, together or separately as they prefer. During these meeting with the research officer, the research officer will clarify the details of the study, its aims and objectives and what is required from the participants and what the benefits and possible drawbacks for the participants might be. The parents/carers will be offered the possibility of opting into a FDT intervention and the nature of the intervention will be described and information sheets will be available should the young person or the parents/carers have misplaced those initially provided. The research officer will also explain how to contact the FDT team should parents/carers decide to take part in this intervention. Consent

to participate in the study will be sought. Parents/carers will be asked to read and sign two consent forms, one to consent to being participants and one to consent to the young person's participation in the study. Young people will be provided with an assent form. Should young people or their parents/carers be undecided as to whether they wish to participate, they will be given up to 24h following the meeting with the research officer to decide. Consent will need to be obtained from both the young person and their parents/carers in order for them both to be enrolled in the research. If consent is obtained, the research officer will send a letter to the participant's GP to inform them of the participants involvement in the research project. Meanwhile, the research assistant, to be appointed, will schedule an appointment with the young person for the collection of the quantitative data and a separate appointment with the parents/carers in which initial data will be collected.

Information for participants (provide actual consent forms and information sheets) including if appropriate, the summary of the study that will appear on SONA to inform participants about the study. N.B. This should be a brief factual description of the study and what participants will be required to do.
Further details: See Participant information Sheets.

Approval of relevant professionals (e.g., GPs, Consultants, Teachers, parents etc.)
Further details: Young people and their parents/carers who fulfil the inclusion criteria will be identified by DBT clinicians across North Wales during their routine discussion of referrals to the DBT Programme. If they consent to participate in the research their care-coordinator in the CAMHS team will be informed as well as their GP. Parents/Carers GP will also be informed of parent/carer participation in this research project.

Payment to: participants, investigators, departments/institutions
Further details: Not Applicable

Equipment required and its availability
Further details: Audio-recording equipment for the research assistant and BCUHB video-recorders for the family therapists and for the research assistant. All equipment is available.

If students will be engaged a project involving children, vulnerable adults, one of the neurology patient panels or the psychiatric patient panel, specify on a separate sheet the arrangements for training and supervision of students. (See guidance notes)
Further details: Trainee Clinical Psychologist will be involved in analysing therapy-session video-recordings and will not have contact with participants. Research Assistant, Research Officer and Trainee Clinical Psychologist will all be supervised by Dr Michaela Swales.

If students will be engaged in a project involving use of MRI or TMS, specify on a separate sheet the arrangements for training and supervision of students. (See guidance notes)
Further details: Not Applicable

What arrangements are you making to give feedback to participants? The responsibility is yours to provide it, not participants' to request it.
Further details: Following the data analysis a summary of main findings will be sent by post to parents/carers and young people and their views (agreement/disagreement) on such findings will be sought and integrated in the write up of the study.

Finally, check your proposal conforms to BPS Guidelines on Ethical Standards in research and sign the declaration. If you have any doubts about this, please outline them.

Amendment form

Participants' ability to give informed, voluntary consent
No

Participants' ability to voluntarily withdraw from the research
No

In questionnaire-based studies, participants' option to omit questions
No

Maintenance of confidentiality of participant data
No

The ability to give a full participant debriefing
No

Risks to participants, investigators, or the institution

Do you intend to use additional questionnaires, please attach copies with supporting documents.
No

Does the nature of your request entails changes to consent/debriefing information, please attach the amended documents with supporting documents.
Yes
Further details: Minor changes to participant information sheet for young person. Changes were suggested by North Wales Clinical Psychology Service User Panel

Amendment declaration

Declaration of ethical compliance: This research project will be carried out in accordance with the guidelines laid down by the British Psychological Society and the procedures determined by the School of Psychology at Bangor. I understand that I am responsible for the ethical conduct of the research. I confirm that I am aware of the requirements of the Data Protection Act and the University's Data Protection Handbook, and that this research will comply with them.
Yes

Declaration of risk assessment: The potential risks to the investigator(s) for this research project have been fully reviewed and discussed. As an investigator, I understand that I am responsible for managing my safety and that of participants throughout this research. I will immediately report any adverse events that occur as a consequence of this research.
Yes

Declaration of conflicts of interest: To my knowledge, there is no conflict of interest on my part in carrying out this research.
Yes

Declaration of data ownership and IPR (for students): I understand that any data produced through this project are owned by the University and must be made available to my supervisor on request or at the end of the project. I confirm that I am aware of the University¿s Intellectual Property Policy and that this research will comply with it.
Yes

Part 4: Research Insurance

Is the research to be conducted in the UK?
Yes

Is the research based solely upon the following methodologies? Psychological activity, Questionnaires, Measurements of physiological processes, Venepuncture, Collections of body secretions by non-invasive methods, The administration by mouth of foods or nutrients or variation of diet other than the administration of drugs or other food supplements
Yes

Research that is based solely upon certain typical methods or paradigms is less problematic from an insurance and risk perspective. Is your research based solely upon one or more of these methodologies? Standard behavioural methods such as questionnaires or interviews, computer-based reaction time measures, standardised tests, eye-tracking, picture-pointing, etc; Measurements of physiological processes such as EEG, MEG, MRI, EMG, heart-rate, GSR (not TMS or tCS as they involve more than simple 'measurement'); Collections of body secretions by non-invasive methods, venepuncture (taking of a blood sample), or asking participants to consume foods and/or nutrients (not including the use of drugs or other food supplements or caffine).
Yes

ETHICS APPENDIX II

Email confirming Bangor University School of Psychology Ethical Approval and Amendment Approval

From: ethics@bangor.ac.uk

Date: 04/01/2016

Dear Stephanie,

2016-15597 A feasibility study on the provision of a Family Domains Therapy intervention for the parents/carers of self-harming young people undergoing Dialectical Behaviour Therapy in North Wales

Your research proposal number 2016-15597
has been reviewed by the Psychology Ethics and Research Committee
and the committee are now able to confirm ethical and governance approval for the above research on the basis described in the application form, protocol and supporting documentation. This approval lasts for a maximum of three years from this date.

Ethical approval is granted for the study as it was explicitly described in the application

If you wish to make any non-trivial modifications to the research project, please submit an amendment form to the committee, and copies of any of the original documents reviewed which have been altered as a result of the amendment. Please also inform the committee immediately if participants experience any unanticipated harm as a result of taking part in your research, or if any adverse reactions are reported in subsequent literature using the same technique elsewhere.

From: ethics@bangor.ac.uk

Date: 08/03/2016

Dear Stephanie,

2016-15597-A13704 Amendment to to A feasibility study on the provision of a Family Domains Therapy intervention for the parents/carers of self-harming young people undergoing Dialectical Behaviour Therapy in North Wales

Your research proposal number 2016-15597-A13704
has been reviewed by the Psychology Ethics and Research Committee
and the committee are now able to confirm ethical and governance approval for the above research on the basis described in the application form, protocol and supporting documentation. This approval lasts for a maximum of three years from this date.

Ethical approval is granted for the study as it was explicitly described in the application

If you wish to make any non-trivial modifications to the research project, please submit an amendment form to the committee, and copies of any of the original documents reviewed which have been altered as a result of the amendment. Please also inform the committee immediately if participants experience any unanticipated harm as a result of taking part in your research, or if any adverse reactions are reported in subsequent literature using the same technique elsewhere.

ETHICS APPENDIX III

Research Project Liability Insurance

Hasilwood House
60 Bishopsgate
London EC2N 4AW
Tel: 020 7847 8670
Fax: 020 7847 8689

UMAL

TO WHOM IT MAY CONCERN

20th July 2015

Dear Sir/Madam

BANGOR UNIVERSITY
AND ALL ITS SUBSIDIARY COMPANIES

Clinical Trials Coverage

We confirm that the above Institution is a Member of U.M. Association Limited, and that the following cover is currently in place in respect Clinical Trials undertaken within the United Kingdom subject to the cover terms, conditions and exceptions.

Certificate of Entry No.	UM026/95
Period of Cover	1st August 2015 to 31st July 2016
Limit of Indemnity	£30,000,000 any one claim and in the aggregate including claims costs and expenses
Basis of Cover	Legal Liability or No Fault cover
Cover provided by	U.M. Association Limited and Excess Cover Providers led by QBE Insurance (Europe) Limited
Main Cover Exclusions	i) Trials involving subjects under 5 years of age ii) Trials assisting with or altering in any way the process of conception iii) Trials investigating or participation in methods of contraception iv) Trials involving genetic engineering other than for preventing and diagnosing disease v) Trials involving drugs or surgery or nutrients vi) Trials involving persons known to be pregnant vii) Trials involving products manufactured by the University

Yours faithfully

Susan Wilkinson
For U.M. Association Limited

ISO 9001 REGISTERED FIRM

U.M. Association Limited
Registered Office: Hasilwood House, 60 Bishopsgate, London, EC2N 4AW
Registered in England and Wales No. 2731799

ETHICS APPENDIX IV

NHS REC Ethics Proposal: IRAS form

NHS REC Form | Reference: 16/WA/0025 | IRAS Version 5.2.0

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Feasibility of offering family domains therapy alongside DBT

1. Is your project research?

(•) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product
( ) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
(•) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
( ) Study involving qualitative methods only
( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
( ) Study limited to working with data (specific project only)
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?

( ) Yes (•) No

2b. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation? ( ) Yes (•) No
b) Will you be taking new human tissue samples (or other human biological samples)? ( ) Yes (•) No
c) Will you be using existing human tissue samples (or other human biological samples)? ( ) Yes (•) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

- [ ] England
- [ ] Scotland
- [x] Wales
- [ ] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- ○ England
- ○ Scotland
- ◉ Wales
- ○ Northern Ireland
- ○ This study does not involve the NHS

4. Which review bodies are you applying to?

- [ ] HRA Approval
- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] Research Ethics Committee
- [ ] Confidentiality Advisory Group (CAG)
- [ ] National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

◉ Yes ○ No

6. Do you plan to include any participants who are children?

◉ Yes ○ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

(•) Yes ( ) No

Please describe briefly the involvement of the student(s):
Doctoral Clinical Psychology Trainee to analyse qualitative data.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

(•) Yes ( ) No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

( ) Yes (•) No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

( ) Yes (•) No

Integrated Research Application System
Application Form for Other clinical trial or investigation

NHS Health Research Authority

Application to NHS/HSC Research Ethics Committee

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Feasibility of offering family domains therapy alongside DBT

Please complete these details after you have booked the REC application for review.

REC Name:
Wales REC 5

REC Reference Number:
16/WA/0025

Submission date:

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

A feasibility study investigating the provision of a Family Domains Therapy (FDT) intervention for the parents/carers of self-harming young people undergoing Dialectical Behaviour Therapy (DBT) in North Wales

A2-1. Educational projects

Name and contact details of student(s):

Student 1

	Title	Forename/Initials	Surname
	Mrs	Stefania	Pethica
Address	50 Kensington Avenue		
	Old Colwyn		
	Colwyn Bay		
Post Code	LL29 9ST		
E-mail	psp4fd@bangor.ac.uk		
Telephone	07510144837		

Fax

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
Doctoral course in Clinical Psychology

Name of educational establishment:
Bangor University

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Dr	Michaela	Swales
Address	North Wales Clinical Psychology Programme		
	Bangor University		
	Bangor, Gwynedd		
Post Code	LL57 2DG		
E-mail	M.Swales@bangor.ac.uk		
Telephone			
Fax			

Academic supervisor 2

	Title	Forename/Initials	Surname
	Dr	Mike	Jackson
Address	North Wales Clinical Psychology Programme		
	Bangor Univeristy		
	Bangor, Gwynedd		
Post Code	LL57 2DG		
E-mail	Mike.Jackson@bangor.ac.uk		
Telephone			
Fax			

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	**Academic supervisor(s)**
Student 1 Mrs Stefania Pethica	☑ Dr Michaela Swales ☑ Dr Mike Jackson

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- ○ Student
- ◉ Academic supervisor
- ○ Other

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	Michaela	Swales
Post	Consultant Clinical Psychologist & Senior Lecturer		
Qualifications	PhD: Psychological processes of change in adolescents in a residential setting MPhil: Psychopathology MPhil: History & Philosophy of Science BA (Hons): Natural Science British Psychological Society: Diploma of Clinical Psychology		
Employer	BCUHB		
Work Address	North Wales Clinical Psychology Programme Bangor University Bangor, Gwynedd		
Post Code	LL57 2DG		
Work E-mail	m.swales@bangor.ac.uk		
* Personal E-mail	m.swales@bangor.ac.uk		
Work Telephone	01248382552		
* Personal Telephone/Mobile			
Fax			

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Mr	Hefin	Francis
Address	School of Psychology Adeilad Brigantia Penrallt Road Gwynedd Bangor		
Post Code	LL57 2AS		
E-mail	h.francis@bangor.ac.uk		
Telephone	+44 (0) 1248 388339		
Fax	+44 (0) 1248 38 2599		

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	
Sponsor's/protocol number:	
Protocol Version:	1
Protocol Date:	01/11/2015
Funder's reference number:	
Project website:	

Registry reference number(s):

The Department of Health's Research Governance Framework for Health and Social Care and the research governance frameworks for Wales, Scotland and Northern Ireland set out the requirement for registration of trials. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

International Standard Randomised Controlled Trial Number (ISRCTN):

ClinicalTrials.gov Identifier (NCT number):

Additional reference number(s):

Ref.Number Description	Reference Number

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

Self-harm includes any act of intentional self-poisoning or self-injury regardless of motivation and includes acts with suicidal intent and those without. Self-harm in adolescence is a major public health problem. The behaviour occurs in about 10% of adolescents, often repeated and is the strongest predictor of suicide. Suicide is the second cause of death in adolescence (Patton, 2009). Self-harm exacts a distressing toll on young people and their families and is expensive in terms of health and social costs. Young people with repetitive self-harm often fail to achieve in education and go on to have persistent mental health problems.

Recent literature shows that a modified version of Dialectical Behaviour Therapy (DBT) that includes parents in the treatment has the potential to significantly reduce self-harming behaviour in adolescents (Mehlum et al, 2014). Thus, said intervention required young people and their parents/carers to participate together in a group intervention, which might in itself be a barrier to taking part in the intervention for young people who experience high levels of conflict in their relationship with their parents/carers.

This feasibility study will examine the acceptability of providing a new kind of family intervention to the parents/carers of young people undergoing DBT – Family Domains Therapy (FDT). FDT was developed by Prof Jonathan Hill in conjunction with local BCUHB employed family therapists, who will deliver FDT in this study. If the FDT intervention proves acceptable to parents then we plan to proceed to a RCT that will examine whether the addition of FDT to DBT augments the clinical outcomes of young people receiving DBT. In preparation for a future RCT, therefore, we intend to use several measures of the young-person's symptoms, coping strategies and problem solving ability pre and post-DBT to assess the practicalities and acceptability of collecting these data in this population.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to

consider.

There are three issues of concern that may arise from participants taking part in this study.

1. Self-harming young people experiencing emotional dysregulation are a client group that is at high risk. Those consenting to participate in this study will already be involved in active treatment for high risk behaviours. All young people will be treated actively by CAMHS clinicians who are expert in managing these problems, whether they take part in the research intervention or not. Furthermore, DBT has robust risk management procedures which are followed at all times and specifically target high risk behaviours (Linehan, 1993). If the young person discloses self-harming behaviours or is at risk of harm, said robust risk management procedures which are part of everyday clinical practice will be followed. If parents report to the family therapist about young person's risk taking, self-harm or exposure to risk, the same robust risk management procedures will be followed. All procedures following a disclosure of exposure to serious harm will be made clear to both young people and their families in their initial appointment with the DBT therapist as the risk management procedures are part of treatment as usual.

2. Young people taking part in the study will be required to complete additional questionnaires and interviews (see Methodology). This might involve discussing distressing topics. The clinicians delivering said questionnaires and interviews are all trained with working with this population and all of these additional measures are routinely used in other services. To ensure young people are supported throughout this procedure, should interviews and/or questionnaires prove distressing, every young person will have access to their CAMHS clinician following completion of additional measures. Young people will be reminded that they can drop out of the research at any point without being asked any questions. In addition, as a routine part of DBT, young people will have access to the telephone number of their assigned clinician to contact if they experience distress related to their condition or related to the research procedures throughout their treatment.

3. All young people referred for DBT and their parents/carers will be offered the opportunity to take part in the research project. Within the research project parents/carers will be offered the possibility of accessing a novel intervention: Family Domains Therapy (FDT). Parents/carers who do not opt into the research will still be able to access non-specified family interventions as currently provided by their local services. Participation in research will not affect provision of local services or what young people or parents/carers are offered (treatment as usual). Some distress might be caused to parents/carers from discussing family issues during the FDT intervention, however this would be no different to the potential for distress in other types of family intervention/therapy. The family therapists conducting the FDT intervention are all trained and supervised by the developer of FDT. FDT takes a non-judgemental and compassionate stance towards all family members.

4. Parents/carers will be included in the study if they and their young person consent to be part in the research.

5. A qualitative interview will be conducted with parents/carers only at the end of their involvement with FDT or of their young person's DBT treatment (if parents/carers not involved in FDT). Although discussing family matters may cause some distress commonly people find it helpful to articulate their experience and their point of view. The final interview will allow parents/carers to give their opinion on the treatment they have received and contribute to the development of a novel intervention. Parents/Carers will be informed that they can choose to stop the interview at any time.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply:*

- ☐ Case series/ case note review
- ☐ Case control
- ☐ Cohort observation
- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology
- ☑ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☑ Qualitative research

☑ Questionnaire, interview or observation study

☐ Randomised controlled trial

☐ Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

The main predictions of this study relate to feasibility and are as follows:
1. Data necessary for the evaluation of both FDT and DBT will be collected from at least 80% of participants.
2. At least 50% of parents/carers participants will opt into the Family Domains Therapy.
Additionally, qualitative data will be collected via interviews and video recordings of therapy sessions, to explore how parents decide whether to take part in the FDT intervention and what their view of the intervention is.

The main objective of this study is to test the feasibility and acceptability of offering a Family Domains Therapy (FDT) intervention to the parents/carers of young people undergoing the DBT programme as a potential enhancing element of outcomes for young people. In order to do this it is important to assess the feasibility and acceptability of assessing both outcomes and predictors of outcomes of DBT and FDT and to assess uptake of the intervention ahead of the planning a larger fully powered RCT.

The study is divided in two parts:
PART 1. This part of the study answers the question:
Can data evaluating progress in treatment be systematically collected from young people in North Wales DBT programmes?

PART 2. This part of the study answers four questions:
1. How many parents/carers of young people undergoing DBT choose to take up Family Domains Therapy (FDT)?
2. Can we collect from parents/carers the data necessary to evaluate FDT?
3. How do parents/carers make the decision to opt in or out of FDT?
4. What do parents/carers find helpful about FDT?

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

Background

Self-harm includes any act of intentional self-poisoning or self-injury regardless of motivation and, therefore, includes acts with suicidal intent and those without. Self-harm in adolescence is a major public health problem. The behaviour is highly prevalent (occurring in about 10% of adolescents), often repeated and is the strongest predictor of subsequent suicide. Self-harm exacts a distressing toll on young people and their families and is expensive in terms of health and social costs. Young people with repetitive self-harm often fail to achieve in education and go on to have persistent mental health problems.

Suicide is the second most common cause of death in adolescence (Patton et al., 2009). Increased severity of self-harm is associated with higher levels of depression, anxiety and impulsivity (Madge et al., 2011), and patients who escalate the severity of their self-harm are at high risk of completed suicide (Carter, Reith, Whyte & McPherson, 2005). Strangulation and attempted hanging in adolescents have increased, both of which are strongly associated with completed suicide (Runeson, Tidemalm, Dahlin, Lichtenstein & Langstrom, 2010). Amongst young female suicide victims, 81% have engaged in self-harm (Zahl & Hawton, 2004). Repetition of self-harm behaviour is common with repetition rates of between 10-15% within a year and up to 42% for follow-up periods longer than a year (Brent, 1997). Longitudinal studies indicate that repeated self-harm in adolescence is not only a risk factor for subsequent suicide but also carries heightened risk of psychiatric disorders into adulthood. Intervening early will benefit the young people themselves but also deliver healthcare savings. The average health service cost for an adolescent who self-harms is high at £8,058 per person per year plus £7,314 per person per year social costs. Effective treatments for adolescents who repeatedly self-harm and who are at high risk of subsequent suicide are desperately needed.

Previous studies of interventions for adolescent self-harm have rarely proved effective. One exception to this is a recently published study that applied Dialectical Behaviour Therapy (DBT), an established efficacious treatment originally developed for adult women with a history of repetitive self-harm in the context of borderline personality

disorder. Mehlum and colleagues (2014), in a study conducted in Oslo, demonstrated efficacy for DBT with self-harming adolescents. In this study, parents were included in the psychoeducation component of the DBT treatment – a departure from the standard DBT protocol utilized with adults – previously described by Miller, Rathus, Linehan, Wetzler and Leigh (1997). Whilst this study is a welcome development in demonstrating that there is at least one effective intervention for repeated self-harm in adolescents, the particular protocol utilized restricts the flexibility of the intervention. Many adolescents with repeated self-harm may not live with their parents or may have highly conflicted relationships with them, which would preclude their participation in DBT for adolescents as tested by Mehlum and colleagues. Studies would indicate that adolescents not living with their family and those with high levels of family conflict may be especially vulnerable to suicidal behaviour and thus it is of concern that a potentially effective intervention would be denied them by insisting on parental participation or a particular form of parental participation. In addition, a key task of adolescence is to individuate from parents with peers as an important source of support for this process. The psychoeducation group component of DBT offers a unique opportunity for peer support in problem solving that may be inhibited for some adolescents in the presence of their parents. We, therefore, propose to further refine and test an alternative family and carer intervention to deliver alongside DBT that will preserve the benefits of involving parents in the treatment, whilst increasing flexibility by offering support to carers other than parents, and maintain the benefit of an adolescent only psycho-educational group for skills training.

DBT was originally developed to treat women with a history of repetitive self-harm in the context of Borderline Personality Disorder (BPD). DBT is one of the most well-established treatments for this client group as indicated in a recent Cochrane Review (Stoffers et al 2013) and is also recommended by NICE (NCCMH, 2009). Following on from its promise in addressing repeated self-harm many researchers and clinicians adapted and evaluated the impact of DBT in treating adolescents with a history of self-harming (Woodberry & Popenoe, 2008). A recent meta-analysis of 19 RCTs of interventions for self-harm in adolescents has in fact indicated that DBT is the most promising intervention for this population (Ougrin, Tranah, Stahl, Moran & Asarnow, 2015).

Linehan's biosocial model of BPD conceptualises self-harming and suicidal behaviour as the result of emotion dysregulation. Emotion dysregulation refers to the inability to regulate emotions coupled with high emotional vulnerability. This means that the emotionally dysregulated individual is sensitive to emotional stimuli, experiences emotions intensely and for longer than would normally be the case. Emotion dysregulation is described by Linehan (1993) as the result of biological disposition, environmental context and the transaction between the two. Part of DBT involves providing skills for emotional modulation, however, young people are often still living in an environmental context which may continually precipitate and / or reinforce emotional dysregulation. Unlike adults, young people have little control over their environment, and studies have shown that addressing parents in family-centred intervention can bring about benefits for the whole family unit, including decreasing parental depressive symptomatology (Huey et al. 2004; Woodberry & Popenoe, 2008). Furthermore, involving the family unit is consistent with the DBT approach, as an attempt to reduce environmental pressures on the young person.

Recently, attempts have been made at providing family interventions alongside DBT for adolescents, however no family therapy model has yet been delineated for this group of young people (Miller, Glinski, Woodberry, Mitchell & Indik, 2002). Miller et al. (2002) have delineated what a potential theoretical synthesis between DBT and family therapy (FT) might look like. They indicate that the "dialectical" philosophy, which views reality as an interrelated system in continuous change is compatible with a systems perspective which views family life as composed of multiple stories and views of each family member. According to Miller et al. a DBT informed family therapy approach would take a compassionate and non-judgemental stance towards parents' experiences, validating the pain and guilt that families with problematic adolescents might be experiencing and labelling behaviours as problematic rather than families. Such an approach would ideally intervene by reducing family interactions that contribute to adolescent life-threatening behaviour, reduce parental behaviour that interferes with treatment, reduce family interactions that interfere with the families' quality of life and increase families' behavioural skills in identifying triggers and potential solutions to crisis situations.

Family Domains Therapy (FDT) was outlined by Hill, Fonagy, Safier and Sargent in 2003. It proposes a model of how problematic family interactions are constructed which allows families to reflect on how each family member expresses their needs and goes about getting their needs met. FDT highlights how there needs to be a shared understanding within a family in order for communication and actions to make sense to every family member. In other words, the family needs to be able to communicate about what their interaction is about. The experience of invalidation occurs when there is a misunderstanding between the child and the adult over what the nature of the interaction is. This misunderstanding can occur either due to a failure of the parent to understand the child's needs, or due to a confused or mixed expression of needs by the child. FDT therefore sees the experience of invalidation as emerging in interaction and takes a compassionate and non-judgemental stance towards all family members. According to FDT a "domain" is the combination of a child expressing his or her needs and the parent's response (Child's need + Parent's response = Domain). When children signal their needs clearly, and parents respond in ways that address them, the domain is referred to as being clear and matched: the parents' response matches the child's need. When domains are clear and matched, parents and children understand what is going on, and where there are problems, they know how they are to be addressed. When domains are unclear or unmatched, for example if the child is not signalling his or her needs clearly there can be misunderstandings about what is going on, and parents and children

can feel angry, hurt or upset. FDT highlights four domains of interaction between parent and child based on the kind of needs the child can express and the parents' response. Three domains (attachment, safety and discipline) involve interactions that require a response from the parents; attachment involves acts of comforting, safety involves acts of protection and discipline involves acts of boundary setting and containment, in these three domains parental action is required in order to regulate the child's emotion. The fourth domain, exploration, involves an interaction which does not require parental action but interested curiosity, this kind of interaction increases shared knowledge and can occur only in a state of emotional regulation. FDT provides psychoeducation to parents regarding the impact of parenting emotionally vulnerable children and the emotional and behavioural changes that can be expected in adolescents; it informs parents of the domains approach and how this can help communication and increase parental reflective skills and capacity to identify the needs of the young person and respond coherently and consistently to those expressed needs. It helps parents manage the dialectics of safety versus attachment, safety versus discipline, attachment versus exploration, etc. FDT meets all the requirements that Miller et al (2002) have outlined as necessary to DBT informed family therapy intervention. It also addresses problems that parents of self-harming and suicidal adolescents have identified as areas they need support in: communication and family relationships (Byrne et al., 2008).

Overall there appears to be a clear need for the development of a family therapy model consistent with the DBT approach that supports parents/carers of self-harming young people to create an environment that can accommodate the young person's emotional vulnerability and to establish whether adding family interventions to DBT augments its effectiveness. This study will assess the acceptability of Family Domains Therapy as a potential family therapy model to be used to support the parents/carers of self-harming young people alongside DBT; it will also address the practicalities of evaluating the DBT Programmes across North Wales.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

Study Aims and Predictions

This study has two parts.
PART 1 aims to assesses the feasibility, practicalities and acceptability of the recruitment and assessment procedures that would be needed to systematically assess outcome in any future RCT of DBT augmented with FDT.
PART 2 aims to assesses the uptake and acceptability of Family Domains Therapy (FDT) intervention to the parents/carers of young people undergoing the DBT programme ahead of a larger fully powered RCT. In order to determine this we will assess the percentage of parents/carers who opt into the FDT intervention, the decision making process by which parents choose to opt in or out of FDT, the perceived helpfulness and benefits of the intervention, both session-by-session and at the end of the intervention.

The main predictions of this study are:
1. We expect 50% of self-harming young people referred to CAMHS for DBT and their parents/carers to consent to participate in the research.
2. PART 1. We expect to be able to collect all the data necessary from 80% of young people who have agreed to participate in the study. This would be our criterion for feasibility. We expect measures to indicate a reduction in self-harming behaviour in the young people undergoing DBT, although, this is not a primary measure of outcome as this study is a feasibility pilot.
3. PART 2. We expect to be able to collect all the data necessary from 80% of parents/carers who have agreed to participate in the study. We expect that 50% of parents who agree to take part in the study will also opt into the FDT intervention. This would be our criterion for feasibility.
These figures have been drafted based on local clinicians' experiences of young people and parental involvement in local Child and Adolescent Mental Health Services (CAMHS).

Methodology

Design
PART 1. This part of the study answers the question:
Can data evaluating progress in treatment be systematically collected from young people in North Wales DBT programmes?
This part of the study uses a descriptive methodology involving a single group design, consisting of young people aged 14 to 18 who have been referred to DBT Programmes across North Wales. This part of the study will audit the process, feasibility and acceptability of recruiting young people to the study and collecting pre-post treatment data from questionnaires and semi-structured interviews. The data collected will concern potential outcomes, mediators and predictors of outcomes for young people undergoing DBT.

PART 2. This part of the study answers four questions:
1. How many parents/carers of young people undergoing DBT choose to take up Family Domains Therapy (FDT)?
2. Can we collect from parents/carers the data necessary to evaluate FDT?
3. How do parents/carers make the decision to opt in or out of FDT?
4. What do parents/carers find helpful about FDT?
This part of the study uses a mixed-methodology involving a single group design, consisting of the parents/carers of the young people referred for DBT.
Quantitative data will include the percentage of parents who opt into FDT and percentage of parents/carers who complete all pre- and post-treatment measures.
Qualitative data will be collected to investigate the decision-making process by which parents choose to opt in or out of FDT, and the perceived helpfulness and benefits of the intervention. This data will include a semi-structured interview, session-by-session qualitative feedback forms, and video-recordings of FDT sessions.

Participants
The study will aim to recruit 20 young people and their parents/carers from local CAMHS.

The following inclusion and exclusion criteria will be adopted when recruiting participants:
Inclusion Criteria:

Young People: -
1) The young person meets referral criteria of the DBT Programme in his/her local CAMHS (this typically includes a minimum of 5 out of 9 criteria for Borderline Personality Disorder plus self-harming behaviour).
2) The young person is aged between 14 and 18.
3) The young person is willing and able to consent to the research.
Parents/Carers:-
1) Parents and Carers of the young person who is willing and able to consent to the research.
Exclusion Criteria:

Young People: -
1) Intellectual Disability.
2) Acute Psychosis.
3) Lack of capacity to consent.
Parents/Carers:-
1) Intellectual Disability.
2) Acute Psychosis.
3) Lack of capacity to consent.

Recruitment

Young people and their parents/carers who fulfil the inclusion criteria will be identified by DBT clinicians across North Wales during their routine discussion of referrals to the DBT Programme. These perspective participants will be approached by their assigned DBT clinician during their routine initial appointment to introduce the DBT intervention. During this meeting the young person and their parents/carers will receive a brief introduction to the study and its aims, and consent to meet with the research officer, Victoria Garvey, to gain more information about the study will be sought. If they consent they will be asked to sign a consent form, highlighting that they have consented to be contacted by the research officer. Families and young people will be given an information sheet, with details of the study.

The research officer will contact the parents/carers and young people who have consented to be contacted no sooner than 24 hours after their initial meeting with the DBT clinician and will arrange to meet parents/carers and young people, together or separately as they prefer. During these meetings with the research officer, the research officer will clarify the details of the study, its aims and objectives and what is required from the participants and what the benefits and possible drawbacks for the participants might be. The parents/carers will be offered the possibility of opting into a FDT intervention and the nature of the intervention will be described and information sheets will be available should the young person or the parents/carers have misplaced those initially provided. The research officer will also explain how to contact the FDT team should parents/carers decide to take part in this intervention. Consent to participate in the study will be sought. Parents/carers will be asked to read and sign two consent forms, one to consent to being participants and one to consent to the young person's participation in the study. Young people will be provided with an assent form. Should young people or their parents/carers be undecided as to whether they wish to participate, they will be given up to 24h following the meeting with the research officer to decide.

Consent will need to be obtained from both the young person and their parents/carers in order for them both to be enrolled in the research. If consent is obtained, the research officer will send a letter to the participant's GP to inform them of the participant's involvement in the research project. Meanwhile, the research assistant, to be appointed, will schedule an appointment with the young person for the collection of the quantitative data and a separate appointment with the parents/carers in which initial data will be collected.

Study Settings

This study will take place in community CAMHS settings across Betsi Cadwaladr University Health Board.
PART 1. All data from young people will be collected in clinical rooms at the local CAMHS setting by a dedicated psychology assistant employed by BCUHB and trained in the study methodology and in the assessment tools and supervised by Dr Swales.
PART 2. Quantitative data and semi-structured interview data will either be collected at the family home or at their local CAMH service depending on parents' preference by a key researcher (Psychology Assistant or Trainee Clinical Psychologist) employed by BCUHB and trained in the assessment tools. Session-by-session qualitative rating forms and therapy session video-recordings will be collected by the BCUHB employed family therapists delivering FDT on CAMHS premises.

Safeguarding and Risk Management

Participants will be informed that should they disclose information about themselves or others being at serious risk of harm during any of the research procedures, the research team member will have to communicate that information to the young person's assigned DBT clinician and local service safeguarding procedures will be followed as stated on the participant consent forms.
There is a potential risk for researchers collecting data in family homes. Researchers going to family homes will follow local health board and service lone worker policies to ensure they log their absences from the office, and their research supervisor knows where they are, and both researcher and supervisor know emergency procedures. Parents/Carers who take part in this research will be known to services, where there are pre-existing concerns about risk to the researcher home visits for data collection will not be offered.

Ethical Considerations on Participant Information and Anonymity

Participants will be provided with an information sheet explaining the aims of the study. The information sheet will also contain contact details of the research team for any future questions they may have and provide contacts for REC members, should the participants wish to raise concerns about the conduct of the study. Participants will also be informed that the data they provide will remain anonymous and cannot be traced to their identity. The information sheet will also explain their right to withdraw at any time. Following NHS ethics guidelines, participants will also be asked to read and sign consent and assent forms.

Standard procedures to ensure the anonymity and the confidentiality of the data will be adhered to. All participants will be made aware that they may withdraw from the study at any point even after it has been completed. Participants will also be informed that their decision to withdraw at any stage of the study will not affect in any way the treatment they are receiving at their local CAMHS. Young people will all access the DBT programme as they would do ordinarily in CAMHS whether they choose to take part in the research project or not. Parents/Carers will only be able to access Family Domain Therapy (FDT) if they opt into the research, however, they will still be able to access non-specified family therapy (treatment as usual) from the same family therapists that are delivering FDT should they refuse consent to participate in this research project.

Materials and Procedure

The study consists of two parts; PART 1 addresses the feasibility and acceptability of collecting data necessary for the evaluation of Dialectical Behaviour Therapy (DBT) from young people referred to the DBT programme. This data will be collected pre-post the young person's treatment. PART 2 addresses the feasibility and acceptability of offering Family Domains Therapy (FDT), collecting the data necessary for the evaluation of FDT and exploring how parents make the choice to opt into FDT or not, and what they find helpful about it.

PART 1: YOUNG PEOPLE
Once the young person's assent to participate in the research and their parent/carer's consent has been gained, the research assistant, will arrange a meeting with the young person to complete the following assessment questionnaires and semi-structured interviews prior to the commencement of the DBT programme:

a. Borderline Symptom List-23 (Bohus et al., 2009)
The Borderline Symptom List – 23 (BSL-23) was developed as a self-rating instrument to specifically quantify borderline-typical symptomatology. The items are based on the criteria of the DSM-IV, the Diagnostic Interview for Borderline Personality Disorder – revised version, the opinions of clinical expert and borderline patients. The BSL is composed of 23 items that are rated using a 5-point scale (0=not at all, 4=very strong). The BSL has been used in recent RCT of DBT for self-harming adolescents (Mehlum et al., 2014), therefore this measure was included in this study as a potential DBT outcome measure.
b. DBT Ways of Coping Check-list (Neacsiu, Rizvi, Vitaliano, Lynch & Linehan, 2010)

The DBT Ways of Coping Check-list (DBT-WCCL) is a measure of the participant coping skills. It is a 59-item self-report scale. Each item is rated on a 4-point scale (0=never used, 3=regularly used). The DBT-WCCL is composed of two sub-scales the DBT Skills Subscale which assesses coping via the DBT skills and the Dysfunctional Coping Sub-scale (DCS) which assesses coping via dysfunctional means. It is a standard DBT outcome measure as it can successfully discriminate participants who receive skills training from those who don't. Skills training is a crucial mode of treatment in DBT and a significant moderator of symptom reduction (Neasciu et al, 2010).
c. Lifetime Parasuicide Count (Comtois & Linehan, 1999)
The Lifetime Para-suicide Count (LPC) is a semi-structured interview used to measure lifetime history of self-injurious behaviour grouped by method, intent to die, and level of medical treatment. The interview is preceded by an introduction and a definition of para-suicide. The LPC is a standard assessment measure in DBT which is routinely used with adolescent outpatients and has been recently used as assessment tool in an RCT of DBT for self-harming adolescents (Miller, Rathus & Linehan, 2007; Mehlum et al., 2014).
d. Zanarini Rating Scale for Borderline Personality Disorder (Zanarini, 2003)
The Zanarini Rating Scale for Boderline Personality Disorder (ZAN-BPD) is a brief clinician-administered interview to assess severity and change in BPD symptomatology. It has been included in this study as a potential outcome measure of DBT.

The completion of the above-mentioned measures will require approximately one to one and a half hours and might be conducted over two meetings if necessary. On all occasions the young person's assigned DBT clinician will be available to the young person following the data collection to address any distress caused by the completion of questionnaires or the semi-structured interview. The research assistant will also remind the young person that they can ask to terminate the interview at any time without having to give an explanation.

Following this initial data collection parents/carers will be invited to join their young person for a problem-solving assessment. In order to assess problem-solving the research assistant will conduct the Means Ends Problem-Solving Test (Platt & Spivak, 1975) with the young person in the presence of their parents/carers. The Means Ends Problem-Solving Test consists of 5 everyday problem-solving challenges. The young person will be asked how they might go about solving the problem and they will be oriented to discuss / seek advice from their parent/carers if they wish to do so. The interaction will be videotaped to capture their answers and the interaction with the parent. Problem-solving skills are known to be adversely affected in those who self-harm (Nock & Mendes, 2008), and for this reason DBT has a specific focus on skills training (Linehan, 1993). Thus, assessing problem-solving is a way to measure potential outcomes of DBT. Additionally, the presence of the parent/carer will allow assessment of whether and in what way the young person requests help from their parent/carer, the quality of the interaction and the level of helpfulness, all of which are potential outcomes and potential predictors of outcomes of Family Domains Therapy.

After these procedures the young person will commence the DBT Programme. When the young person comes to the end of their DBT treatment, the research assistant will arrange to meet with the young person, and measures a, b, c & d and the Means-Ends Problem-Solving test will be repeated.

PART 2A: PARENTS/CARERS
Once the parents/carers' consent to participate in the research and their consent for the young person to participate in the research is gained (Appendices 18 & 19), the research assistant will arrange a meeting with the parents/carers to complete the following assessment questionnaires:
a. General Health Questionnaire (Goldberg, 1978)
The General Health Questionnaire (GHQ) was developed as a screening instrument to identify psychological distress amongst adults in primary care settings. It is comprised of 60 self-report items on a 4-point scale (0=not at all, 3=more than usual). Research shows that parents/carers of children with behavioural problems often experience significant stress (Mouton & Tuma, 1988; Mash & Johnston, 1983; Patterson, 1982). Parent/carer mental health has been shown to be a barrier to parent/carer engagement in children's treatment (Morrissey-Kane & Prinz, 1999). The GHQ is a non-specific, broad screening tool which was included in this study as it might capture changes in various aspects of parental mental health throughout their young person's treatment and their own engagement in FDT, should they choose to engage with it.
b. Beck Depression Inventory - II (Beck, Steer & Brown, 1996)
The Beck Depression Inventory-II (BDI-II) is the most widely used tool to screen for depression in adult populations. It consists of 21 items to assess the intensity of depression in clinical and normal populations. Each item is a list of four statements arranged in increasing severity about a particular symptom of depression from which the participant must choose the one that best describes the way s/he has been feeling in the past week. The manual provides clinical cut-offs. Research suggests that parents/carers of children with behavioural problems often experience depression (Griest, Wells & Forehand, 1979; Griest & Wells, 1983), that depression can be a barrier to parental engagement and a predictor of parent/carer drop out (Morrissey-Kane & Prinz, 1999; Woodberry and Popenoe, 2008). The BDI-II was included in this study as measuring level of parent/carer depression might be beneficial to predict parental engagement and as a potential outcome measure of the young person's treatment or parents/carers' engagement in FDT.
c. SCORE-15 (Stratton et al., 2013)

The SCORE-15 Index of Family Functioning and Change is a validated self-report outcome measure designed to be sensitive to the kind of changes in family relationships that family therapists see as indications of useful therapeutic change. It is composed of 15 items and six indicators, three of them qualitative. The SCORE-15 was included in this study as potential outcome measure of FDT.
d. Appendix 9 - Parent Child Emotions and Behaviours Questionnaire
The Parent Child Emotions and Behaviours Questionnaire (PCEBQ) is a brief 10 item self-report questionnaire which asks parents/carers to rate their responses on a 5-point scale (0=never, 4=most of the time). The questionnaire was designed as an assessment and outcome tool for Family Domains Therapy (FDT) and it explores the way the parent/carer responds to the child, the parent/carer's understanding of the child's needs and the parent/carer's awareness of the way in which they communicate with their child.
e. Parent Orientation Questionnaire
The Parent Orientation Questionnaire is a brief 11 item self-report questionnaire that was designed for this study. There are 10 quantitative items which request the parent/carer to define the extent of the child's difficulties, their perceived role in the child's recovery, parental readiness to receive help and advice and parental concern on a continuous scale (far left=not at all, far right= a lot). It also includes one open question which explores parental attributions of their child's difficulties. This scale has been devised as a potential assessment tool for Family Domains Therapy (FDT).

Each questionnaire should take no longer than five minutes to complete, overall completion of all questionnaires will require approximately 30 minutes. For each questionnaire participants will be informed that they should only proceed so long as comfortable, that they can stop the meeting at any point and that they do not have to answer every question if they do not wish to do so.

Following the completion of the questionnaires, initial qualitative data will be collected.
The research assistant will collect a Five Minute Speech Sample (Calam & Peters, 2006) of the parents describing their young person, which will be analysed to assess expressed emotion towards the young person. The same procedure will be followed at the end of the young person's treatment, with the addition of a semi-structured interview to explore how the parents/carers decided whether to opt into the FDT intervention or not, and if they have what benefits they ascribe to the treatment. The semi-structured interview should take approximately 45 minutes, bringing the end of treatment data collection meeting to approximately one hour and 15 minutes. This semi-structured interview was constructed using questions from the Change Interview (Elliott, 2008) a qualitative tool to explore post-treatment changes and from the literature on barriers to engagement in therapy (Kazdin, Holland, Crowley, & Breton, 1997)

PART 2B: PARENTS/CARERS WHO OPT FOR FAMILY DOMAIN THERAPY.
In order to explore which specific aspects of Family Domains Therapy parents/carers find useful the following qualitative data will be collected from the parents/carers who choose to undergo Family Domains Therapy. All therapy sessions will be video-recorded as this is a novel intervention. The video-recordings will be used to assist in describing the intervention in more detail for any subsequent research study, for further detailing of the Family Domains Therapy manual and in order to explore which aspects of FDT parents/carers find helpful or hindering. In order to accomplish the latter task, at the end of each therapy session the parents/carers will be asked to complete a Helpful Aspects of Therapy Form (HAT; Llewelyn, 1988) to indicate what aspects of that specific session they found helpful or unhelpful. This form should take approximately 5 minutes to complete. The use of session-by-session rating scales is routine within CAMHS settings, and associated with better outcomes in therapy. The HAT form is a qualitative post-session self-report questionnaire which uses open-ended questions to help clients write down their experiences of helpful and hindering therapy events, rate their helpfulness or unhelpfulness and indicate where in the therapy session they occurred and why they believe such events were helpful or hindering. It is a simple and efficient means of soliciting information from clients about their perceptions of key change processes in therapy. The HAT form is considered a less-intrusive and naturalistic way of collecting data, it becomes a routine part of the participants' overall therapy experiences and appears to help clients process their therapy more effectively (Elliott, 2012). The HAT's open-ended format generates qualitative data of sufficient detail and focus as to lend itself to various uses, including identification of significant events, descriptive and interpretive forms of qualitative data analysis and even quantitative content analysis (Elliott, 2012). When parent/carers near the end of their FDT treatment, the trainee clinical psychologist, Stefania Pethica, will collect all completed HAT forms and identify on video-recordings of therapy sessions the specific interactions that parents/carers have highlighted as helpful. Due to the novel nature of Family Domains Therapy, it is essential to explore what specific aspects of the therapy parents/carers find helpful in order to isolate what the change ingredients of the therapy might be, in view of developing the treatment to undergo a fully powered randomised controlled trial.

Final Debriefing
Following the data analysis a summary of main findings will be sent by post to parents/carers and young people and their views (agreement/disagreement) on such findings will be sought and integrated in the write-up of the study.

Data Analysis
PART1. This part of the study regards the feasibility and acceptability of assessing the outcomes, mediators and predictors of outcomes of DBT in North Wales. Therefore the process of recruitment, ease and acceptability of data collection is of primary interest.
Data analysis will include audit of the number of young people and their parents/carers recruited and the number of participants completing all procedures of data collection.

PART2. This part of the study regards the feasibility and acceptability of offering Family Domains Therapy to the parents/carers of the young people undergoing the DBT programme as well as the feasibility and acceptability of assessing the outcomes, mediators and predictors of outcomes of FDT. Of primary interest is the process of recruitment, ease and acceptability of data collection. Data analysis will include audit of number of parent/carers who opt into FDT and number of parents/carers completing all procedures of data collection.

Due to the novel nature of Family Domains Therapy (FDT), this part of the research also includes the collection of qualitative data to explore how parents make the decision to opt into FDT or not and what they find helpful about FDT. Qualitative interview data collected in the final interview with both parents who have opted into FDT and those who haven't will employ a thematic analysis. Thematic analysis involves the transcription of interviews and the repeated reading of the material in order to highlight sub-themes that emerge from the text. Sub-themes are then collected into larger thematic categories that might be recurrent across several interviews with different individuals. This analysis would allow the understanding of barriers and incentives to engaging in FDT, the acceptability and feasibility of offering FDT according to parents/carers, and for those who participated in FDT the post-treatment benefits they can identify. All of this data will be essential for the future planning of a fully powered randomized controlled trial (RCT) of FDT as it will allow the prediction of potential barriers and incentives to engagement as well as the selection of outcome measures that tap into the outcomes identified by the participants.

Qualitative session-by-session data collected with the Helpful Aspects of Therapy form (HAT) will be used to guide the analysis of helpful processes that occur during the therapy itself. In the HAT form participants highlight what they have found helpful in a specific therapy session, the collection of this data allows the understanding of the immediate effects (micro-outcomes) of important moments in psychotherapy. This data will be used to conduct a quantitative content analysis of what aspects of therapy participants found helpful, it will also indicate in which therapy sessions helpful events occurred. The Trainee Clinical Psychologist, Stefania Pethica, will use the HAT form to identify the helpful event within the therapy session video recording and conduct a dialogical sequence analysis of the helpful event (Linell, 1998; Leiman, 2012). Dialogical sequence analysis involves taking topical episodes in the therapeutic conversation as focus for analysis and transcribing them for analysis. The analysis highlights aspects of the interaction, and what participants are doing in the conversation, how they position themselves towards the speaker and towards the problem being discussed. Investigating which processes parents/carers find helpful may lead to the further understanding of how the family psychotherapy process helps families make sense of their experiences and generate helpful solutions to their difficulties.

Dissemination
DBT team members meet weekly and any information requiring immediate dissemination can be fed back to participants through this route. The research assistant devoted to the project will also take responsibility for contacting participants promptly with any relevant information. The findings of this study will be used in a grant application to systematically evaluate whether FDT can augment the outcomes of DBT.
The findings of this study will also be used for a doctoral thesis by one of the key researchers, Trainee Clinical Psychologist, Stefania Pethica. Additionally, the results of this study may be published in peer-reviewed journals and presented at conferences. Participants will be given contact details for requesting a copy of the results if they so wish.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [ ] Management of the research
- [ ] Undertaking the research
- [ ] Analysis of results
- [x] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.

Participant information sheets and consent forms were circulated amongst the members of the People Panel (the North Wales Clinical Psychology Programme Service User Panel). Their feedback was then incorporated in the paperwork.

Following the data analysis a summary of main findings will be sent to parents/carers and young people and their views (agreement/disagreement) on such findings will be sought and integrated in the write up of the study. DBT team members meet weekly and any information requiring immediate dissemination can be fed through this route. The research assistant devoted to the project will also take responsibility for contacting participants promptly with any relevant information.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

YOUNG PEOPLE RECEIVING DBT INTERVENTION.
a) the young person meets referral criteria of the DBT programme in his or her local CAMHS (this typically includes a minimum of 5 out of 9 criteria for Borderline Personality Disorder plus self-harming behaviour).
b) aged between 14 and 18.
c) willing and able to consent to the research

PARENTS/CARERS OF YOUNG PEOPLE RECEIVING DBT INTERVENTION.
a) parents and carers of the young person who is willing to consent to participate

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

YOUNG PEOPLE AND PARENTS/CARERS EXCLUSION CRITERIA:
a) intellectual disability
b) acute psychosis
c) lack capacity to consent

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Preliminary explanation and information stage - parents/carers and young people.	1	1	5 min	DBT lead when discussing DBT intervention with young person and parents/carers. To take place in a quiet room at local CAMHS.
Detailed information about the study and domains based family therapy. Parents/carers and young people.	1	n/a	30 min	Research Officer. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers. Parents/carers and young person to be seen separately if wished by young person.
General Health Questionnaire. Parents/carers only.	2	n/a	5 min	Research Assistant. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers.Delivered pre-post young person's DBT intervention.

Beck Depression Inventory - II. Parents/carers only	2	n/a	5 min	Research Assistant. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers. Delivered pre-post young person's DBT intervention.
Parent Child Emotions and Behaviours Questionniare - Parents/carers only	2	n/a	5 min	Research Assistant. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers. Delivered pre-post young person's DBT intervention.
Parent Orientation Questionnaire - parents/carers only	2	n/a	5 min	Research Assistant. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers.Delivered pre-post young person's DBT intervention.
SCORE-15 - parents/carers only	1	n/a	5min	Research Assistant. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers.Delivered pre-post young person's DBT intervention.
5 minute speech sample describing young person - parents/carers only	2	n/a	5 min	Research Assistant. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers. One speech sample collected at beginning of research one collected after young person has completed DBT intervention.
Lifetime parasuicide count, semi-structured interview - young person only	2	2	30 min	Research assistant. To take place in a quiet room at local CAMHS. (During this appointment the measures below will also be taken: Borderline symptom checklist-23, Zanarini rating scale)
DBT Ways of coping checklist - young person only	2	2	5 min	Research assistant. To take place in a quiet room at local CAMHS.
Borderline symptom list 23 - young person only	2	2	5 min	Research assistant. To take place in a quiet room at local CAMHS.
Zanarini rating scale for borderline personality disorder - young person only	2	n/a	30 min	Research assistant. To take place in a quiet room at local CAMHS.
Means End Problem Solving Task - young person and parent/carers	2	n/a	30 min	Research assistant. To take place in a quiet room at local CAMHS.
Feedback to young people and parents/carers	1	n/a	5 min	Information about outcome and request of young person's and parent/carers's opinion of findings sent by post with enclosed return envelope included.
Interview on the decision to opt in or out of FDT and its benefits	1	n/a	45min	Research Assistant or Trainee Clinical Psychologist. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers.Delivered pre-post young person's DBT intervention.
Helpful Aspects of Therapy Form	1	n/a	5min	This form is a session-by-session rating form will be collected at the end of each FDT therapy session. It will be collected by the family therapist delivering the intervention. Parents/Carers will complete as many as number of sessions they undergo.

A19. Give details of any clinical intervention(s) or procedure(s) to be received by participants as part of the research protocol. *These include uses of medicinal products or devices, other medical treatments or assessments, mental health interventions, imaging investigations and taking samples of human biological material. Include procedures which might be received as routine clinical care outside of the research.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days).
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4

Standard DBT intervention for young people with emerging borderline personality disorder - individual therapy	20	20	1 hour	Assigned local CAMHS clinician. Intervention will take place at local CAMHS.
Standard DBT intervention for young people with emerging borderline personality disorder - skills training group	22	22	2 hours	Assigned local CAMHS clinician. Intervention will take place at local CAMHS.
Family Domains Therapy intervention for parents/carers	10	n/a	1 hour	Local CAMHS Family therapist. Intervention will take place at local CAMHS. Total number of interventions will depend on family functioning, an estimate of eight sessions per family will be provided. However should families need more sessions they will be provided in accordance with the family's needs.

A20. Will you withhold an intervention or procedure, which would normally be considered a part of routine care?

○ Yes ◉ No

A21. How long do you expect each participant to be in the study in total?

Participants are expected to remain in the study for approximately the length of the standard DBT intervention, which is 20 to 24 weeks.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

For the young people participating in the research will involve completing additional questionnaires and semi-structured interviews which address potentially distressing experiences. The research assistant delivering the intervention will be trained to interrupt the data collection should the participant become distressed. The research assistant will also encourage participants to proceed with the interviews as they feel comfortable and to cease involvement at their own discretion. In addition the young person's assigned clinician will be available following the data collection to discuss any issues raised during the data collection for the participant. It is also part of standard DBT intervention for young people to have their clinician's telephone number to contact if they become unduly distressed during the week.

For the parents/carers, the study involves the completion of questionnaires, providing a speech sample and a follow up interview on decision making process to opt in or out of the family domains therapy intervention and its benefits. Careful instructions and reassurance have been factored into the request for a speech sample, assuring participants to only proceed as they feel comfortable, and to cease involvement at their own discretion. Parents/carers who opt into family domains therapy will potentially experience distress connected with discussing difficult family interactions, this however will be no different than in any other family intervention. All family therapists delivering FDT are experienced in delivering family therapy interventions and supporting parents/carers throughout.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

◉ Yes ○ No

If Yes, please give details of procedures in place to deal with these issues:

Local health board and service procedures will be followed. If a disclosure occurs:
1. the participant will be reminded of the content of the consent forms and the limits of service confidentiality.
2. the research team member conducting the interview or questionnaire will then proceed by contacting the young person/parent/carer's assigned clinician.
Researcher's behaviour in the face of disclosure has been outlined in both Participant Information Sheets and

Consent Forms.

A24. What is the potential for benefit to research participants?

Participation in this study will benefit participants in the following ways:
1) for young people and their parents/carers it will provide an opportunity to make a contribution to research.
2) for parents/carers this research will provide the opportunity to discuss their experience of their young person's behaviour, receive a novel family therapy intervention and to participate in shaping a form of therapy.

A25. What arrangements are being made for continued provision of the intervention for participants, if appropriate, once the research has finished? *May apply to any clinical intervention, including a drug, medical device, mental health intervention, complementary therapy, physiotherapy, dietary manipulation, lifestyle change, etc.*

Young people will receive standard follow up from the DBT intervention as provided by their local services.

Parents/carers receiving FDT intervention will be followed up by their family therapist. The family therapist will consider continuing to offer FDT depending on the feasibility/acceptability of this therapy model highlighted by the research itself. Supportive family therapy will also be available to families at end of the research study in line with the families needs and wishes.

A26. What are the potential risks for the researchers themselves? *(if any)*

There is a potential risk for researchers conducting semi-structured interviews/questionnaires in family homes. Researchers going to family homes will follow local health board lone worker policy to ensure they log their absences from the office, and their research supervisor knows where they are, and researchers know emergency procedure. Families who take part in this research project will be known to services, where there are concerns about risk to the researchers clinic meetings only will be offered.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

Participants will only be identified by local CAMHS care teams. This process will take place during the course of their normal screening of referrals for DBT.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

(●) Yes ( ) No

Please give details below:
Participants will only be identified by local CAMHS care teams. This process will take place during the course of their normal screening of referrals for DBT. Researchers will have access to demographic information and will have access to parents/carers' contact details only with participant consent .

A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

(●) Yes ( ) No

A27-5. Has prior consent been obtained or will it be obtained for access to identifiable personal information?

◉ Yes ○ No

If Yes, please give details below.

Consent to access identifiable personal information, such as contact details, will be obtained by the research assistant in writing as part of the consent to participate in the research project (see Consent to be contacted by researcher forms and consent forms).

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

○ Yes ◉ No

A29. How and by whom will potential participants first be approached?

Participants will be approached by direct care team (DBT clinical lead) as part of routine meeting following referral for DBT intervention for the young person.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

At the initial routine meeting with the DBT clinical lead participants will be provided with a consent form requesting their consent to be contacted by the research officer, together with a brief verbal explanation detailing the purpose and background to the study, and what they will be required to do if taking part. At this stage young people and their parents/carers will be asked to provide written consent to be contacted by the research officer Victoria Garvey and will be provided with an information sheet about the study.

Following the receipt of detailed information the research officer will meet with the parents and carers and young people to discuss the research in more detail and answer any questions that they may have. Young people and their parents / carers will be given the opportunity to opt into the research project. Young people will be asked to sign an assent form, and parents/carers will be asked to sign a participant consent form and a consent form for the young person to participate in the research project. It will be made clear to parents/carers that if they do not opt into the research they will still be able to access other family support offered by CAMHS and to young people that they can access DBT whether or not they consent to research participation. Only when consent to participate in the research is obtained from both parents/carers and the young person will they be enrolled into the study.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◉ Yes ○ No

A31. How long will you allow potential participants to decide whether or not to take part?

During the meeting with the research officer prospective participants might decide to opt in or out of the research or request more time to consider whether they would like to participate. If they request more time they will be given 24h to consider whether they would like to take part in the research project and asked to sign the parent/carer as participant consent form, the parent/carer as guardian consent form and the young person's assent form.

A32. Will you recruit any participants who are involved in current research or have recently been involved in any research prior to recruitment?

- ○ Yes
- ◉ No
- ○ Not Known

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters)*

The nature of some of the tasks included in the study requires a good level of English comprehension, and therefore individuals who do not fulfil this c riteria will not be recruited for the study. This is to both pr eserve the integrity of the data produced, and to prevent wasting the time of and/or causing undue stress or embarrassment to individuals without the required level of English comprehension for the tasks at hand.

A33-2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to participants in Wales?

All consent and information forms will be translated into Welsh.
However, Welsh speaking participants will be informed that data analysis will be conducted in English, thus individuals who would wish to participate in research interviews through the medium of Welsh will not be included in the study.
Welsh speaking participants who chose to opt in will have the opportunity of receiving the clinical interventions (DBT, FDT) through the medium of Welsh in some areas but would need to consent to conducting the research interview through the medium of English.
However, the decision not to participate in the research interviews would not preclude any family or young person from accessing treatment as usual.

A34. What arrangements will you make to ensure participants receive any information that becomes available during the course of the research that may be relevant to their continued participation?

DBT team members meet weekly and any information requiring immediate dissemination can be fed through this route. The Research Assistant devoted to the project will also take responsibility for contacting participants promptly with any relevant information.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

- ○ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- ◉ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- ○ The participant would continue to be included in the study.
- ○ Not applicable – informed consent will not be sought from any participants in this research.
- ○ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?*(Tick as appropriate)*

- [ ] Access to medical records by those outside the direct healthcare team
- [ ] Access to social care records by those outside the direct social care team
- [ ] Electronic transfer by magnetic or optical media, email or computer networks
- [ ] Sharing of personal data with other organisations
- [ ] Export of personal data outside the EEA
- [x] Use of personal addresses, postcodes, faxes, emails or telephone numbers
- [x] Publication of direct quotations from respondents
- [ ] Publication of data that might allow identification of individuals
- [x] Use of audio/visual recording devices
- [x] Storage of personal data on any of the following:
  - [x] Manual files (includes paper or film)
  - [x] NHS computers
  - [ ] Social Care Service computers
  - [ ] Home or other personal computers
  - [x] University computers
  - [ ] Private company computers
  - [x] Laptop computers

Further details:
All participants will be allocated an identifying code unique to them.
All experimental materials will only use this code for id entification, no other details leading to identification will be recorded on such materials.
Codes will be stored separately from personal identifying information.

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

An anonymous ID code will be assigned to each participant and use d as the only identifier in all experimental materials.
The data produced by the study w ill only contain the anonymous identifier codes, and all work done on the data w ill use those codes only.
The master list of personal contact d etails that links to the anonymous ID codes will be kept separa te and securely locked away from all other materials in the offic e of the Chief Investigator (Dr Michaela Swales).
Where direct quotes of participants will be used a pseudonym will be assigned to each participant.
The research team will only have access to demographic data and the personal data that allows them to contact the participants in order to schedule appointments for interviews/data collection.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

Only the research team will have access to participants' persona l data during the study.
Personal data will be kept securely an d separate from all other research data
and only used when required to fulfil the ethical obligations of the study and to contact participants to arrange appointments for data collection.
All necessary work will be carried out with anonymis ed data which will not be
traceable to any individual personal data.
Video and audio recordings will be accessed by researchers on BCUHB premises.

Storage and use of data after the end of the study

A43. How long will personal data be stored or accessed after the study has ended?

- ○ Less than 3 months
- ◉ 3 – 6 months
- ○ 6 – 12 months
- ○ 12 months – 3 years
- ○ Over 3 years

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

○ Yes ◉ No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

◉ Yes ○ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

A49-2. Will you seek permission from the research participants to inform their GP or other health/ care professional?

◉ Yes ○ No

It should be made clear in the participant's information sheet if the GP/health professional will be informed.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

The Department of Health's Research Governance Framework for Health and Social Care and the research governance frameworks for Wales, Scotland and Northern Ireland set out the requirement for registration of trials. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

○ Yes ◉ No

Please give details, or justify if not registering the research.
The research will not be registered as it is a feasibility study and will not have the design or statistical power of a randomised control trial.

Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

☑ Peer reviewed scientific journals
☐ Internal report
☑ Conference presentation
☐ Publication on website
☐ Other publication
☐ Submission to regulatory authorities
☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
☐ No plans to report or disseminate the results
☑ Other (please specify)

Part of the results of the study will be used for a Doctoral Thesis in Clinical Psychology by Trainee Clinical Psychologist Stefania Pethica.

A53. Will you inform participants of the results?

◉ Yes ○ No

Please give details of how you will inform participants or justify if not doing so.
All participants will receive a document through the post outlining the main findings of the study, and participants will be asked for their feedback on the findings (agreement/disagreement). A return envelope will be present in the document.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

☐ Independent external review
☐ Review within a company

- [x] Review within a multi−centre research group
- [x] Review within the Chief Investigator's institution or host organisation
- [x] Review within the research team
- [x] Review by educational supervisor
- [ ] Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
This proposal has been produced by key researcher Stefania Pethica. The study development process has consisted of regular meetings between the Trainee Clinical Psychologist (Stefania Pethica), the Chief Investigator, the Research Assistant and other members of the clinical team delivering the domains based family therapy intervention, involving the close scrutiny of all relevant details to create a well thought through proposal. The outcome of this careful review of the study proposal is a clearly identified research question, a structured plan for completing the research, and a design that has sought to protect the welfare of participants and reduce the burden on participants at every stage.

The proposal has also been reviewed by Dr Mike Jackson(Bangor Unviersity Research Team for the North Wales Clinical Psychology Programme). The outline proposal was also reviewed by the Pathway to Portfolio Grant Awarding Committee in BCUHB that is funding the project.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

- [ ] Review by independent statistician commissioned by funder or sponsor
- [ ] Other review by independent statistician
- [ ] Review by company statistician
- [ ] Review by a statistician within the Chief Investigator's institution
- [ ] Review by a statistician within the research team or multi−centre group
- [x] Review by educational supervisor
- [ ] Other review by individual with relevant statistical expertise
- [x] No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

Title Forename/Initials Surname

Department
Institution
Work Address

Post Code
Telephone
Fax
Mobile
E-mail

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

The primary outcome of the study will be the percentage of young people and parent/carers consented who complete all the measures. The percentage of parents/carers who opt into the FDT intervention. This is a study on the feasibility and acceptability of assessing the outcomes, mediators and predictors of outcomes of FDT and DBT in North Wales. Therefore our interest is in the process of recruitment, ease and acceptability of data collection.
Criteria for feasibility are the following:
-50% of young people and their parent/carers approached agree to take part in the study.
-all data is collected from 80% of participants.
-50% of parents/carers recruited agree to undertake FDT.

Qualitative analysis will be conducted on parent/carer end of treatment interview, session-by-session rating forms and session video recordings which will produce information about what parents/carers find helpful about FDT, and acceptability of FDT.

A58. What are the secondary outcome measures? *(if any)*

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:	20
Total international sample size (including UK):	0
Total in European Economic Area:	0

Further details:
The participants will be young people aged 14 to 17 referred to CAMHS for DBT intervention. And their parents/carers.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

The sample size was decided based on the current levels of referrals to CAMHS for DBT interventions and an estimation of how many referred individuals will accept to take part in the study based on clinical experience.

A61. Will participants be allocated to groups at random?

○ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

1. Audit of number of young people and their parents/carers recruited, number of parents/carers opting into FDT, and number of participants completing all procedures of data collection.
2. Thematic analysis, content analysis and dialogical sequence analysis of qualitative data.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title Forename/Initials Surname Prof Jonathan Hill
Post	Professor of Child and Adolescent Psychiatry
Qualifications	University 1968-1971 Tripos Exams Sidney Sussex College Cambridge Natural Sciences Pt. 1a Medical Sciences Pt. 1a Pt. 1b (Including Experimental Psychology) 1971 B.A. Class 2.1 Clinical Training 1971-1974 St. Thomas Hospital, London Haematology Prize 1974 M.B. B.Chir. General Training in Psychiatry – Maudsley Hospital, London 1979 M.R.C.Psych. 1998 F.R.C.Psych. Senior Registrar Training Scheme in Child Psychiatry, Maudsley Hospital, London Research Training 1984 - 1986 M.R.C. Training Fellowship in the Department of Child and Adolescent Psychiatry, Institute of Psychiatry, London. Supervisor: Professor M Rutter.
Employer	Reading University
Work Address	School of Psychology and Clinical Language Sciences University of Reading, Earley Gate, Reading
Post Code	RG6 6AL
Telephone	
Fax	
Mobile	
Work Email	j.hill@reading.ac.uk

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- (●) NHS or HSC care organisation
- ( ) Academic
- ( ) Pharmaceutical industry
- ( ) Medical device industry
- ( ) Local Authority
- ( ) Other social care provider (including voluntary sector or private organisation)
- ( ) Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation Bangor University School of Psychology
Given name Hefin

Family name	Francis
Address	School of Psychology Adeilad Brigantia
Town/city	Penrallt Road Gwynedd
Post code	LL57 2AS
Country	UNITED KINGDOM
Telephone	+44 (0) 1248 388339
Fax	+44 (0) 1248 38 2599
E-mail	h.francis@bangor.ac.uk

Is the sponsor based outside the UK?

○ Yes ◉ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

☑ Funding secured from one or more funders

☐ External funding application to one or more funders in progress

☐ No application for external funding will be made

What type of research project is this?

◉ Standalone project

○ Project that is part of a programme grant

○ Project that is part of a Centre grant

○ Project that is part of a fellowship/ personal award/ research training award

○ Other

Other – please state:

Please give details of funding applications.

Organisation	BCUHB
Address	R&D Office, Clinical School Ysbyty Gwynedd Penrhosgarnedd BANGOR
Post Code	LL57 2PW
Telephone	01248384384
Fax	
Mobile	
Email	Rossela.Roberts@wales.nhs.uk

Funding Application Status: ◉ Secured ○ In progress

Amount: 38,456

Duration

Years: 2
Months:

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?
Pathway to Portfolio (P2P)

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

○ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	Dr	Nefyn	Williams
Organisation	Betsi Cadwaladr University Health Board		
Address	Clinical Academic Office		
	Ysbyty Gwynedd		
	Bangor		
Post Code	LL57 2PW		
Work Email	nefyn.williams@bangor.ac.uk		
Telephone	01248384877		
Fax			
Mobile			

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/01/2016
Planned end date: 31/03/2017
Total duration:
Years: 1 Months: 2 Days: 31

A71-2. Where will the research take place? *(Tick as appropriate)*

- ☐ England
- ☐ Scotland
- ☑ Wales
- ☐ Northern Ireland
- ☐ Other countries in European Economic Area

Total UK sites in study 1

Does this trial involve countries outside the EU?

○ Yes ◉ No

A72. Which organisations in the UK will host the research? *Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

☐ NHS organisations in England	
☑ NHS organisations in Wales	1
☐ NHS organisations in Scotland	
☐ HSC organisations in Northern Ireland	
☐ GP practices in England	
☐ GP practices in Wales	
☐ GP practices in Scotland	
☐ GP practices in Northern Ireland	
☐ Joint health and social care agencies (eg community mental health teams)	
☐ Local authorities	
☐ Phase 1 trial units	
☐ Prison establishments	
☐ Probation areas	
☐ Independent (private or voluntary sector) organisations	
☐ Educational establishments	
☐ Independent research units	
☐ Other (give details)	
Total UK sites in study:	1

A75-1. What arrangements will be made to review interim safety and efficacy data from the trial? Will a formal data monitoring committee or equivalent body be convened?

No DMEC. DBT therapists and Family therapists will also have weekly meeting to discuss outcomes and risk management.

If a formal DMC is to be convened, please forward details of the membership and standard operating procedures to the Research Ethics Committee when available. The REC should also be notified of DMC recommendations and receive summary reports of interim analyses.

A75-2. What are the criteria for electively stopping the trial or other research prematurely?

Not applicable, as all additionally provided interventions (FDT) in this study will be provided according to participants needs and wishes. Participants will be informed that they can interrupt interviews for data collection should they wish to and this will not have an impact on their treatment.

A76. Insurance/ indemnity to meet potential legal liabilities

Note: in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (NHS sponsors only)

☑ Other insurance or indemnity arrangements will apply (give details below)

Bangor University Indemnity scheme will apply.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☑ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☐ Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

A77. Has the sponsor(s) made arrangements for payment of compensation in the event of harm to the research participants where no legal liability arises?

○ Yes ◉ No

Please enclose a copy of relevant documents.

PART B: Section 7 - Children

1. Please specify the potential age range of children under 16 who will be included and give reasons for carrying out the research in this age group.

Young people with self-harming behaviour aged 14 to 18 referred to CAMHS for a DBT intervention will be included in the study.Self-harm includes any act of intentional self-poisoning or self-injury regardless of motivation and, therefore, includes acts with suicidal intent and those without. Self-harm in adolescence is a major public health problem. The

behaviour is highly prevalent (occurring in about 10% of adolescents), often repeated and is the strongest predictor of subsequent suicide. Self-harm exacts a distressing toll on young people and their families and is expensive in terms of health and social costs. Young people with repetitive self-harm often fail to achieve in education and go on to have persistent mental health problems.

Suicide is the second most common cause of death in adolescence (Patton et al., 2009). Increased severity of self-harm is associated with higher levels of depression, anxiety and impulsivity (Madge et al., 2011), and patients who escalate their severity of self-harm are at high risk of completed suicide (Carter, Reith, Whyte & McPherson, 2005). Strangulation and attempted hanging in adolescents have increased, both of which are strongly associated with completed suicide (Runeson, Tidemalm, Dahlin, Lichtenstein & Langstrom, 2010). Amongst young female suicide victims, 81% have engaged in self-harm (Zahl & Hawton, 2004). Repetition of self-harm behaviour is common with repetition rates of between 10-15% within a year and up to 42% for follow-up periods longer than a year (Brent, 1997). Longitudinal studies indicate that repeated self-harm in adolescence is not only a risk factor for subsequent suicide but also carries heightened risk of psychiatric disorders into adulthood. Intervening early will benefit the young people themselves but also deliver healthcare savings. The average health service cost for adolescent who self-harm is high at £8,058 per person per year plus £7,314 per person per year social costs. Effective treatments for adolescents who repeatedly self-harm and who are at high risk of subsequent suicide are desperately needed.

Previous studies of interventions for adolescent self-harm have rarely proved effective. One exception to this is a recently published study that applied Dialectical Behaviour Therapy (DBT) an established as efficacious treatment originally developed for adult women with a history of repetitive self-harm in the context of borderline personality disorder. Mehlum and colleagues (2014), in a study conducted in Oslo, demonstrated efficacy for DBT with for self-harming adolescents. In this study, parents were included in the psychoeducation component of the DBT treatment – a departure from the standard DBT protocol utilized with adults - previously described by Miller, Rathus, Linehan, Wetzler and Leigh (1997). Whilst this study is a welcome development in demonstrating that there is at least one effective intervention for repeated self-harm in adolescents, the particular protocol utilized restricts the flexibility of the intervention. Many adolescents with repeated self-harm may not live with their parents or may have highly conflicted relationships with them, which would preclude their participation in DBT for adolescents as tested by Mehlum and colleagues. Studies would indicate that adolescents not living with their family and those with high levels of family conflict may be especially vulnerable to suicidal behaviour and thus it is of concern that a potentially effective intervention would be denied them by insisting on parental participation or a particular form of parental participation. In addition, a key task of adolescence is to individuate from parents with peers as an important source of support for this process. The psychoeducation group component of DBT offers a unique opportunity for peer support in problem solving that may be inhibited for some adolescents in the presence of their parents. We, therefore, propose to further refine and test an alternative family & carer intervention to deliver alongside DBT that will preserve the benefits of involving parents in the treatment, whilst increasing flexibility by offering support to carers other than parents, and maintain the benefit of an adolescent only psycho-educational group for skills training.

DBT was originally developed to treat women with a history of repetitive self-harm in the context of Borderline Personality Disorder (BPD). DBT is one of the most well-established treatments for this client group as indicated in a recent Cochrane Review (Stoffers et al 2013) and is also recommended by NICE (NCCMH, 2009). Following on from its promise in addressing repeated self-harm many researchers and clinicians adapted and evaluated the impact of DBT in treating adolescents with a history of self-harming (Woodberry & Popenoe, 2008). A recent meta-analysis of 19 RCTs of interventions for self-harm in adolescents has in fact indicated that DBT is the most promising intervention for this population (Ougrin, Tranah, Stahl, Moran & Asarnow, 2015).

Linehan's biosocial model of BPD conceptualises self-harming and suicidal behaviour as the result of emotion dysregulation. Emotion dysregulation refers to the inability to regulate emotions coupled with high emotional vulnerability. This means that the emotionally dysregulated individual is sensitive to emotional stimuli, experiences emotions intensely and for a longer period of time. Emotion dysregulation is described by Linehan (1993) as the result of biological disposition, environmental context and the transaction between the two. Part of DBT involves providing skills for emotional modulation, however, young people are often still living in an environmental context which may continually precipitate and / or reinforce emotional dysregulation. Unlike adults, young people have little control over their environment, and studies have shown that addressing parents in family-centred intervention can bring about benefits for the whole family unit, including decreasing parental depressive symptomatology (Huey et al. 2004; Woodberry & Popenoe, 2008). Furthermore, involving the family unit is consistent with the DBT approach, as an attempt to reduce environmental pressures on the young person.

Recently, attempts have been made at providing family interventions alongside DBT for adolescents, however no family therapy model has yet been delineated for this group of young people (Miller, Glinski, Woodberry, Mitchell & Indik, 2002). Miller et al. (2002) have delineated what a potential theoretical synthesis between DBT and family therapy might look like. They indicate that the "dialectical" philosophy, which views reality as an interrelated system in continuous change is compatible with a systems perspective which views family life as composed of multiple stories and views of each family member. According to Miller et al. a DBT informed family therapy approach would take a compassionate and non-pejorative stance towards parents' experiences, validating the pain and guilt that families

with problematic adolescents might be experiencing and labelling behaviours as problematic rather than families. Such an approach would ideally intervene by reducing family interactions that contribute to adolescent life-threatening behaviour, reduce parental behaviour that interferes with treatment, reduce family interactions that interfere with families' quality of life and increase families' behavioural skill in identifying triggers and potential solutions to crisis situations.

2. Indicate whether any children under 16 will be recruited as controls and give further details.

No, all young people (14 to 18) will receive active treatment.

3-2. Please describe the arrangements for seeking informed consent from a person with parental responsibility and/or from children able to give consent for themselves.

In the first meeting between the care team (assigned DBT clinician) and the young person and their parents/carers, the information about the research project will be shared.
Consent in writing to be contacted by the research officer to gain more information about the research project will be sought from both parents/carers and the young person. Where both the parents/carers and young person consent to be contacted by the research officer each will be given an information sheet with details of the aims of the study, what the potential benefits and drawbacks are for participants. Following this the research officer will meet with parents/carers and the young person individually and seek consent to participate in the research. Only where both parents/carers and young person consent to participate in the research will the family be enrolled in the study.

4. If you intend to provide children under 16 with information about the research and seek their consent or agreement, please outline how this process will vary according to their age and level of understanding.

The information will be provided by the care team (DBT lead clinician) and the Research Officer in a way that is appropriate to the young person's understanding. An information sheet tailored to young people and what the research project requires of them will be used.
Parents/carers will also be informed in the initial meeting with the assigned DBT clinician and consent forms and explanatory information will also be provided for them.

Copies of written information sheet(s) for parents and children, consent/assent form(s) and any other explanatory material should be enclosed with the application.

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.*

Research site		Investigator/ Collaborator/ Contact	
Institution name	Betsi Cadwaladr University Health Board Trust	Title	Dr
Department name	Child and Adolescent Mental Health Services	First name/ Initials	Michaela
Street address	Croesnewydd Rd	Surname	Swales
Town/city	Wrexham		
Post Code	LL13 7TD		

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.
9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.
10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
11. I understand that the main REC or its operational managers may share information in this application or supporting documentation with the Medicines and Healthcare products Regulatory Agency (MHRA) where it is relevant to the Agency's statutory responsibilities.
12. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

- ◯ Chief Investigator
- ◯ Sponsor
- ◯ Study co-ordinator
- ◯ Student
- ◯ Other – please give details
- ◯ None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☐ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Dr Michaela Swales on 04/01/2016 19:34.

Job Title/Post:	Consultant Psychologist
Organisation:	BCUHB
Email:	m.swales@bangor.ac.uk

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by Mr Hefin Francis on 05/01/2016 14:43.

Job Title/Post:	School Manager for Psychology
Organisation:	Bangor University
Email:	h.francis@bangor.ac.uk

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by Dr Mike Jackson on 05/01/2016 10:53.

Job Title/Post:	Clinical Psychologist
Organisation:	BCUHB
Email:	mike.jackson@wales.nhs.uk

Academic supervisor 2

This section was signed electronically by Dr Michaela Swales on 04/01/2016 19:39.

Job Title/Post:	Consultant Psychologist
Organisation:	BCUHB
Email:	m.swales@bangor.ac.uk

ETHICS APPENDIX V

North Wales REC Favourable Opinion Letter

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Gwasanaeth Moeseg Ymchwil
Research Ethics Service

Ariennir gan **Lywodraeth Cymru**
Funded by **Welsh Government**

Pwyllgor Moeseg Ymchwil Cymru 5
Wales Research Ethics Committee 5
Bangor

Clinical Academic Office
Ysbyty Gwynedd Hospital
Betsi Cadwaladr University Health Board
Bangor, Gwynedd
LL57 2PW

Telephone/ Facsimile: 01248 - 384.877
Email: Rossela.Roberts@wales.nhs.uk
Website : www.nres.nhs.uk

22 January 2016

Dr Michaela Swales
North Wales Clinical Psychology Programme
Bangor University
Brigantia Building, College Road
Bangor, Gwynedd
LL57 2DG m.swales@bangor.ac.uk

Dear Dr Swales,

Study title:	**A feasibility study investigating the provision of a Family Domains Therapy (FDT) intervention for the parents/carers of self-harming young people undergoing Dialectical Behaviour Therapy (DBT) in North Wales**
REC reference:	**16/WA/0025**
IRAS project ID:	**186533**

The Research Ethics Committee reviewed the above application at the meeting held on 21 January 2016. Thank you for attending to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Dr Rossela Roberts, rossela.roberts@wales.nhs.uk
Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below. .

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Summary of discussion at the meeting

Ethical issues raised by the Committee in private discussion, together with responses given by you when invited to join the meeting

The Chairman welcomed you and introduced the Committee members.
The following issues were discussed:

Recruitment arrangements and access to health information; fair participant selection
The Committee discussed the recruitment method, the fairness of the inclusion and exclusion

criteria, and whether any incentives or payments are made.
The Committee was satisfied that the selection of participants has taken into account the patients' clinical care, participants will be recruited fairly and sufficient details are provided in the protocol regarding the inclusion and exclusion criteria.
A query was raised in relation to intellectual disability as an exclusion criteria, how is this assessed and whether this is assessed by the research team.
You clarified that intellectual disability is an exclusion criteria for the DBT intervention not solely for the study and the CAMHS teams make this assessment based on general presentation information; CAMHS will have carried out this assessment for its service users and will not refer / identify a person with intellectual disability as a suitable participant for the study; the research team will not run additional diagnostic assessments.

Informed Consent process and the adequacy and completeness of participant information
The Committee discussed the provision of information to research participants about the purpose of the research, its procedures, potential risks, benefits, and alternatives, and whether it includes all procedures as described in the protocol.
The Committee noted that written informed consent is taken as part of a process - with participants having adequate time to consider the information, and opportunity to ask questions. The language used is understandable to the research participants, the information is clear as to what the participant consents to, and there is no inducement or coercion.
The Committee agreed that the procedures described in the protocol have been adequately addressed in the Information Sheet, but felt that minor amendments could be made to ensure that individuals understand the information and can make a voluntary informed decision to enrol and continue to participate.
The Committee felt that in the Information Sheet for Parents/Carers, the paragraph "What will happen to me or my young person if we do not want to take part" could be construed as coercive and the research team might want to re-phrased it, to emphasize the ability to continue to have access to the routine clinical practice support and therapeutic interventions and not the inability to access the 'new intervention' – but this is an advisory view and not a condition of ethical approval.

The Chairman thanked you for your availability to speak to this submission and gave you an opportunity to ask questions. You did not raise any issues.
The Chairman confirmed that the Committee will deliberate and will be in touch shortly.

Other ethical issues were raised and resolved in preliminary discussion before your attendance at the meeting

Based on the information provided, the Committee was satisfied with the following aspects of the research:

- Social or scientific value; scientific design and conduct of the study
- Recruitment arrangements and access to health information, and fair participant selection
- Favourable risk benefit ratio; anticipated benefit/risks for research participants
- Care and protection of research participants; respect for participants' welfare and dignity
- Informed consent process and the adequacy and completeness of participant information
- Suitability of the applicant and supporting staff
- Independent review
- Suitability of supporting information
- Suitability of the summary of the research

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
REC Application Form [REC_Form_06012016]		06 January 2016
Research protocol or project proposal [DBT and FDT project Protocol]	1	04 November 2015
Summary, synopsis or diagram (flowchart) of protocol in non technical language	1	04 November 2015
Letters of invitation to participant [Parent/Carer Consent to Be Contacted By Research and Consent for Young Person to be Contacted by Researcher]	2	16 December 2015
Letters of invitation to participant [Young Person Assent to be Contacted by Researcher]	2	16 December 2015
Participant information sheet (PIS) [Participant Information Sheet for Parents/Carers]	2	16 December 2015
Participant information sheet (PIS) [Participant Information Sheet for Young Person]	2	16 December 2015
Participant information sheet (PIS) [Parent/Carer Information Sheet on Family Domains Therapy]	2	16 December 2015
Participant consent form [Consent Form Parent/Carer as Guardian]	2	16 December 2015
Participant consent form [Assent Form Young Person]	2	16 December 2015
Participant consent form [Consent Form Parent/Carer as Participant]	2	16 December 2015
GP/consultant information sheets or letters [GP letter]	1	04 November 2015
Interview schedules or topic guides for participants [Interview Protocol of decision to opt in or not and benefits of Family Domains Therapy]	1	04 November 2015
Interview schedules or topic guides for participants [Means Ends Problem Solving Task Instructions]	-	-
Interview schedules or topic guides for participants [Five Minute Speech Sample Manual]	2	14 March 2005
Interview schedules or topic guides for participants [Zanarini Rating Scale for Borderline Personality Disorder]	2003	-
Interview schedules or topic guides for participants [Lifetime Parasuicide Count]	1996	-
Validated questionnaire [Borderline Symptom List 23]	06/2007	-
Validated questionnaire [DBT Ways of Coping Checklist]	-	-
Validated questionnaire [General Health Questionnaire]	1978	-
Validated questionnaire [Beck Depresssion Inventory 2]	1996	-
Validated questionnaire [SCORE 15]	-	-
Non-validated questionnaire [Parent-Child Emotions and Behaviours Questionnaire]	1	04 November 2015
Non-validated questionnaire [Parent Orientation Questionnaire]	1	04 November 2015
Non-validated questionnaire [Helpful Aspects of Therapy Form]	1	04 November 2015
Summary CV for Chief Investigator [Michaela Swales]	-	-
Summary CV for student [Stefania Pethica]	-	-
Summary CV for Academic Supervisor [Mike Jackson]	-	-
Other [Summary CV for Co-Investigator Jonathan Hill]		
Other [Summary CV for Research Officer Victoria Garvey]		13 November 2015
Evidence of Sponsor insurance or indemnity [UMAL insurance certificate]		20 July 2015
Other [Bangor University School of Psychology confirmation of ethical approval of project]	-	04 January 2016

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.
No declarations of interest were made in relation to this application

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

16/WA/0025	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Rossela Roberts

Dr Philip Wayman White, MBChB, FRCGP
Chair
E-mail: rossela.roberts@wales.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

SL-AR2 After ethical review - research oth

Copy to:	Sponsor:	Mr Hefin Francis School of Psychology Bangor Universit Brigantia Building, Penrallt Road Bangor, Gwynedd LL57 2AS h.francis@bangor.ac.uk
	Academic Supervisor:	Dr Mike Jackson School of Psychology Bangor Universit Brigantia Building, Penrallt Road Bangor, Gwynedd LL57 2AS j.hutchings@bangor.ac.uk
	R&D Office	Miss Debra Slater Betsi Cadwaladr University Health Board Clinical Academic Office Ysbyty Gwynedd Hospital Bangor, LL57 2PW debra.slater@wales.nhs.uk

Wales Research Ethics Committee 5

Attendance at Committee meeting on 21 January 2016

Committee Members

Name	*Profession*	*Capacity*	*Present*
Dr Karen BE Addy	Clinical Psychologist	Expert	Yes
Dr Swapna Alexander	Consultant Physician	Expert	Yes
Mrs Kathryn Chester	Research Nurse	Expert	Yes
Ms Geraldine Jenson	Retired College Vice-Principal	Lay +	No
Mr Eliezer Lichtenstein	Student	Lay +	No
Dr Mark G Lord	Consultant Pathologist	Expert	Yes
Dr Pamela A Martin-Forbes	WCRW Research Officer	Expert	Yes
Dr Paul G Mullins	Reader, MRI Physicist	Lay +	No
Mr Vishwanath Puranik	Associate Specialist ENT Surgeon	Expert	Yes
Mrs Lynn C Roberts	Matron, Emergency Department	Expert	No
Dr Judith L Roberts	Research Officer	Expert	Yes
Mrs Rachel L Roberts-Jones	Student	Lay +	Yes
Dr Jason D Walker	Consultant Anaesthetist (Vice-Chairman)	Expert	Yes
Dr Philip W White	General Practitioner (Chairman)	Expert	Yes
Ms Sydna A Williams	Lecturer	Lay +	Yes

In attendance

Name	*Position (or reason for attending)*
Dr Rossela Roberts	Clinical Governance Officer / RES Manager

ETHICS APPENDIX VI

Notification of Non-substantial Minor Amendment

Partner Organisations:
Health Research Authority, England
NIHR Clinical Research Network, England
NHS Research Scotland
NISCHR Permissions Co-ordinating Unit, Wales
HSC Research & Development, Public Health Agency, Northern Ireland

Notification of Non-Substantial/Minor Amendments(s) for NHS Studies

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.
If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

Instructions for using this template

- For guidance on amendments refer to http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/
- This template should be completed by the CI and optionally authorised by Sponsor, if required by sponsor guidelines.
- This form should be submitted according to the instructions provided for NHS/HSC R&D at http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/which-review-bodies-need-to-approve-or-be-notified-of-which-types-of-amendments/ . If you do not submit your notification in accordance with these instructions then processing of your submission may be significantly delayed.

1. Study Information

Full title of study:	Feasibility of offering family domains therapy alongside DBT
IRAS Project ID:	186533
Sponsor Amendment Notification number:	1
Sponsor Amendment Notification date:	08.03.2016
Details of Chief Investigator:	
Name [first name and surname]	Dr Michaela Swales
Address:	North Wales Clinical Psychology Programme / Rhaglen Seicoleg Clinigol Gogledd Cymru, School of Psychology / Ysgol Seicoleg Bangor University / Prifysgol Bangor BANGOR
Postcode:	LL57 2DG
Contact telephone number:	Tel: +44 (0)1248 382552
Email address:	m.swales@bangor.ac.uk
Details of Lead Sponsor:	

Partner Organisations:
Health Research Authority, England NIHR Clinical Research Network, England
NHS Research Scotland NISCHR Permissions Co-ordinating Unit, Wales
HSC Research & Development, Public Health Agency, Northern Ireland

Name:	Bangor University School of Psychology Mr Hefin Francis Adeilad Brigantia Penrallt Road Gwynedd LL57 2AS United Kingdom
Contact email address:	h.francis@bangor.ac.uk
Details of Lead Nation:	
Name of lead nation *delete as appropriate*	Wales
If England led is the study going through CSP? *delete as appropriate*	Not applicable
Name of lead R&D office:	Debra Slater

2. Summary of amendment(s)

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.
If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

No.	Brief description of amendment *(please enter each separate amendment in a new row)*	Amendment applies to *(delete/ list as appropriate)*		List relevant supporting document(s), including version numbers *(please ensure all referenced supporting documents are submitted with this form)*		R&D category of amendment *(category A, B, C) For office use only*
		Nation	Sites	Document	Version	
1	Move the following paragraph from page 2 to page 1. "**Why have I been invited to take part?** We are inviting all the young people who have been referred for DBT in North Wales and their parents/carers to take part in this research. "	**Wales**	**All sites or list affected sites**	Participant Information Sheet for Young Person_V.3_02032016	3	
2	Add the following sentence to the aforementioned paragraph. "We have sent you this information via your DBT therapist so your personal information is completely confidential and you are free to decide if you want to take part, or no. If you decide "No" then that isn't a problem! However, we do hope you can help."	As above				
3	Change the following header **Will my taking part be kept confidential?** To: **If I do take part, will it be confidential?**	As above				
4	Add "you can mention it to your DBT therapist" to the section headed **What if something goes wrong?** On page 4. Note: Our service user panel pointed out that young people of this particular population (self-	As above				

Partner Organisations:
Health Research Authority, England NIHR Clinical Research Network, England
NHS Research Scotland NISCHR Permissions Co-ordinating Unit, Wales
HSC Research & Development, Public Health Agency, Northern Ireland

	harming/suicidal) might not feel comfortable calling people they don't know (university or BCUHB staff) to complain about the research. However, they might feel comfortable speaking to their individual therapist who can then support them in making a complaint.					

[Add further rows as required]

Partner Organisations:
Health Research Authority, England NIHR Clinical Research Network, England
NHS Research Scotland NISCHR Permissions Co-ordinating Unit, Wales
HSC Research & Development, Public Health Agency, Northern Ireland

3. Declaration(s)

Declaration by Chief Investigator

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment(s) to be implemented.

Signature of Chief Investigator: ……..……..…..

Print name: Dr Michaela Swales

Date: 09.03.2016

Optional Declaration by the Sponsor's Representative (as per Sponsor Guidelines)

The sponsor of an approved study is responsible for all amendments made during its conduct.

The person authorising the declaration should be authorised to do so. There is no requirement for a particular level of seniority; the sponsor's rules on delegated authority should be adhered to.

- I confirm the sponsor's support for the amendment(s) in this notification.

Signature of sponsor's representative: ……..……..……

Print name:……..……..……

Post: ……..……..……

Organisation:……..……..……

Date:……..……..

ETHICS APPENDIX VII

Non-substantial Minor Amendment Approval Letter

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Gwasanaeth Moeseg Ymchwil
Research Ethics Service

Ariennir gan **Lywodraeth Cymru**
Funded by **Welsh Government**

Pwyllgor Moeseg Ymchwil Cymru 5
Wales Research Ethics Committee 5
Bangor

Clinical Academic Office
Ysbyty Gwynedd Hospital
Betsi Cadwaladr University Health Board
Bangor, Gwynedd
LL57 2PW

Telephone/ Facsimile: 01248 - 384.877
Email: Rossela.Roberts@wales.nhs.uk
Website : www.nres.nhs.uk

14 March 2016

Dr Michaela Swales
North Wales Clinical Psychology Programme
Bangor University
Brigantia Building, College Road
Bangor, Gwynedd
LL57 2DG m.swales@bangor.ac.uk

Dear Dr Swales,

Study title: **A feasibility study investigating the provision of a Family Domains Therapy (FDT) intervention for the parents/carers of self-harming young people undergoing Dialectical Behaviour Therapy (DBT) in North Wales**
REC reference: **16/WA/0025**
Amendment number: **1**
Amendment date: **08 March 2016**
IRAS project ID: **186533**

Thank you for your letter of 08 March 2016, notifying the Committee of the above amendment.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Notice of Minor Amendment	1	08 March 2016
Participant information sheet (PIS) [Participant Information Sheet for Young Person]	3	02 March 2016

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

16/WA/0025:	Please quote this number on all correspondence

Yours sincerely

Rossela Roberts

Rossela Roberts
RES Manager

E-mail: rossela.roberts@wales.nhs.uk

Copy to:

Sponsor:	Mr Hefin Francis School of Psychology Bangor Universit Brigantia Building, Penrallt Road Bangor, Gwynedd LL57 2AS h.francis@bangor.ac.uk
Academic Supervisor:	Dr Mike Jackson School of Psychology Bangor Universit Brigantia Building, Penrallt Road Bangor, Gwynedd LL57 2AS j.hutchings@bangor.ac.uk
R&D Office	Miss Debra Slater Betsi Cadwaladr University Health Board Clinical Academic Office Ysbyty Gwynedd Hospital Bangor, LL57 2PW debra.slater@wales.nhs.uk

ETHICS APPENDIX VIII

NHS R&D Application Form

NHS R&D Form IRAS Version 5.2.0

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Feasibility of offering family domains therapy alongside DBT

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product

( ) Clinical investigation or other study of a medical device

( ) Combined trial of an investigational medicinal product and an investigational medical device

(●) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

( ) Study limited to working with data (specific project only)

( ) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?

( ) Yes (●) No

2b. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation? ( ) Yes (●) No

b) Will you be taking new human tissue samples (or other human biological samples)? ( ) Yes (●) No

c) Will you be using existing human tissue samples (or other human biological samples)? ( ) Yes (●) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

- [ ] England
- [ ] Scotland
- [x] Wales
- [ ] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- ○ England
- ○ Scotland
- ◉ Wales
- ○ Northern Ireland
- ○ This study does not involve the NHS

4. Which review bodies are you applying to?

- [ ] HRA Approval
- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] Research Ethics Committee
- [ ] Confidentiality Advisory Group (CAG)
- [ ] National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

◉ Yes ○ No

6. Do you plan to include any participants who are children?

◉ Yes ○ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

(•) Yes ( ) No

Please describe briefly the involvement of the student(s):
Doctoral Clinical Psychology Trainee to analyse qualitative data.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

(•) Yes ( ) No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

( ) Yes (•) No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

( ) Yes (•) No

Integrated Research Application System
Application Form for Other clinical trial or investigation

NHS/HSC R&D Form (project information)

Please refer to the Submission and Checklist tabs for instructions on submitting R&D applications.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Feasibility of offering family domains therapy alongside DBT

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

A feasibility study investigating the provision of a Family Domains Therapy (FDT) intervention for the parents/carers of self-harming young people undergoing Dialectical Behaviour Therapy (DBT) in North Wales

A2-1. Educational projects

Name and contact details of student(s):

Student 1

	Title	Forename/Initials	Surname
	Mrs	Stefania	Pethica
Address	50 Kensington Avenue		
	Old Colwyn		
	Colwyn Bay		
Post Code	LL29 9ST		
E-mail	psp4fd@bangor.ac.uk		
Telephone	07510144837		
Fax			

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
Doctoral course in Clinical Psychology

Name of educational establishment:
Bangor University

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Dr	Michaela	Swales
Address	North Wales Clinical Psychology Programme		
	Bangor University		
	Bangor, Gwynedd		
Post Code	LL57 2DG		
E-mail	M.Swales@bangor.ac.uk		
Telephone			
Fax			

Academic supervisor 2

	Title	Forename/Initials	Surname
	Dr	Mike	Jackson
Address	North Wales Clinical Psychology Programme		
	Bangor Univeristy		
	Bangor, Gwynedd		
Post Code	LL57 2DG		
E-mail	Mike.Jackson@bangor.ac.uk		
Telephone			
Fax			

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
Student 1 Mrs Stefania Pethica	☑ Dr Michaela Swales ☑ Dr Mike Jackson

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- ○ Student
- ◉ Academic supervisor
- ○ Other

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	Michaela	Swales
Post	Consultant Clinical Psychologist & Senior Lecturer		
Qualifications	PhD: Psychological processes of change in adolescents in a residential setting MPhil: Psychopathology MPhil: History & Philosophy of Science		

	BA (Hons): Natural Science British Psychological Society: Diploma of Clinical Psychology
Employer	BCUHB
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** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Mr	Hefin	Francis
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A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	
Sponsor's/protocol number:	
Protocol Version:	1
Protocol Date:	01/11/2015
Funder's reference number:	
Project website:	

Registry reference number(s):
The Department of Health's Research Governance Framework for Health and Social Care and the research governance frameworks for Wales, Scotland and Northern Ireland set out the requirement for registration of trials. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

International Standard Randomised Controlled Trial Number (ISRCTN):
ClinicalTrials.gov Identifier (NCT number):

Additional reference number(s):

Ref.Number Description	Reference Number

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

Self-harm includes any act of intentional self-poisoning or self-injury regardless of motivation and includes acts with suicidal intent and those without. Self-harm in adolescence is a major public health problem. The behaviour occurs in about 10% of adolescents, often repeated and is the strongest predictor of suicide. Suicide is the second cause of death in adolescence (Patton, 2009). Self-harm exacts a distressing toll on young people and their families and is expensive in terms of health and social costs. Young people with repetitive self-harm often fail to achieve in education and go on to have persistent mental health problems.

Recent literature shows that a modified version of Dialectical Behaviour Therapy (DBT) that includes parents in the treatment has the potential to significantly reduce self-harming behaviour in adolescents (Mehlum et al, 2014). Thus, said intervention required young people and their parents/carers to participate together in a group intervention, which might in itself be a barrier to taking part in the intervention for young people who experience high levels of conflict in their relationship with their parents/carers.

This feasibility study will examine the acceptability of providing a new kind of family intervention to the parents/carers of young people undergoing DBT – Family Domains Therapy (FDT). FDT was developed by Prof Jonathan Hill in conjunction with local BCUHB employed family therapists, who will deliver FDT in this study. If the FDT intervention proves acceptable to parents then we plan to proceed to a RCT that will examine whether the addition of FDT to DBT augments the clinical outcomes of young people receiving DBT. In preparation for a future RCT, therefore, we intend to use several measures of the young-person's symptoms, coping strategies and problem solving ability pre and post-DBT to assess the practicalities and acceptability of collecting these data in this population.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

There are three issues of concern that may arise from participants taking part in this study.

1. Self-harming young people experiencing emotional dysregulation are a client group that is at high risk. Those consenting to participate in this study will already be involved in active treatment for high risk behaviours. All young people will be treated actively by CAMHS clinicians who are expert in managing these problems, whether they take part in the research intervention or not. Furthermore, DBT has robust risk management procedures which are followed at all times and specifically target high risk behaviours (Linehan, 1993). If the young person discloses self-harming behaviours or is at risk of harm, said robust risk management procedures which are part of everyday clinical practice will be followed. If parents report to the family therapist about young person's risk taking, self-harm or exposure to risk, the same robust risk management procedures will be followed. All procedures following a disclosure of exposure to serious harm will be made clear to both young people and their families in their initial appointment with the DBT

therapist as the risk management procedures are part of treatment as usual.

2. Young people taking part in the study will be required to complete additional questionnaires and interviews (see Methodology). This might involve discussing distressing topics. The clinicians delivering said questionnaires and interviews are all trained with working with this population and all of these additional measures are routinely used in other services. To ensure young people are supported throughout this procedure, should interviews and/or questionnaires prove distressing, every young person will have access to their CAMHS clinician following completion of additional measures. Young people will be reminded that they can drop out of the research at any point without being asked any questions. In addition, as a routine part of DBT, young people will have access to the telephone number of their assigned clinician to contact if they experience distress related to their condition or related to the research procedures throughout their treatment.

3. All young people referred for DBT and their parents/carers will be offered the opportunity to take part in the research project. Within the research project parents/carers will be offered the possibility of accessing a novel intervention: Family Domains Therapy (FDT). Parents/carers who do not opt into the research will still be able to access non-specified family interventions as currently provided by their local services. Participation in research will not affect provision of local services or what young people or parents/carers are offered (treatment as usual). Some distress might be caused to parents/carers from discussing family issues during the FDT intervention, however this would be no different to the potential for distress in other types of family intervention/therapy. The family therapists conducting the FDT intervention are all trained and supervised by the developer of FDT. FDT takes a non-judgemental and compassionate stance towards all family members.

4. Parents/carers will be included in the study if they and their young person consent to be part in the research.

5. A qualitative interview will be conducted with parents/carers only at the end of their involvement with FDT or of their young person's DBT treatment (if parents/carers not involved in FDT). Although discussing family matters may cause some distress commonly people find it helpful to articulate their experience and their point of view. The final interview will allow parents/carers to give their opinion on the treatment they have received and contribute to the development of a novel intervention. Parents/Carers will be informed that they can choose to stop the interview at any time.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply:*

- ☐ Case series/ case note review
- ☐ Case control
- ☐ Cohort observation
- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology
- ☑ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☑ Qualitative research
- ☑ Questionnaire, interview or observation study
- ☐ Randomised controlled trial
- ☐ Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

The main predictions of this study relate to feasibility and are as follows:
1. Data necessary for the evaluation of both FDT and DBT will be collected from at least 80% of participants.
2. At least 50% of parents/carers participants will opt into the Family Domains Therapy.
Additionally, qualitative data will be collected via interviews and video recordings of therapy sessions, to explore how

parents decide whether to take part in the FDT intervention and what their view of the intervention is.

The main objective of this study is to test the feasibility and acceptability of offering a Family Domains Therapy (FDT) intervention to the parents/carers of young people undergoing the DBT programme as a potential enhancing element of outcomes for young people. In order to do this it is important to assess the feasibility and acceptability of assessing both outcomes and predictors of outcomes of DBT and FDT and to assess uptake of the intervention ahead of the planning a larger fully powered RCT.

The study is divided in two parts:
PART 1. This part of the study answers the question:
Can data evaluating progress in treatment be systematically collected from young people in North Wales DBT programmes?

PART 2. This part of the study answers four questions:
1. How many parents/carers of young people undergoing DBT choose to take up Family Domains Therapy (FDT)?
2. Can we collect from parents/carers the data necessary to evaluate FDT?
3. How do parents/carers make the decision to opt in or out of FDT?
4. What do parents/carers find helpful about FDT?

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

Background

Self-harm includes any act of intentional self-poisoning or self-injury regardless of motivation and, therefore, includes acts with suicidal intent and those without. Self-harm in adolescence is a major public health problem. The behaviour is highly prevalent (occurring in about 10% of adolescents), often repeated and is the strongest predictor of subsequent suicide. Self-harm exacts a distressing toll on young people and their families and is expensive in terms of health and social costs. Young people with repetitive self-harm often fail to achieve in education and go on to have persistent mental health problems.

Suicide is the second most common cause of death in adolescence (Patton et al., 2009). Increased severity of self-harm is associated with higher levels of depression, anxiety and impulsivity (Madge et al., 2011), and patients who escalate the severity of their self-harm are at high risk of completed suicide (Carter, Reith, Whyte & McPherson, 2005). Strangulation and attempted hanging in adolescents have increased, both of which are strongly associated with completed suicide (Runeson, Tidemalm, Dahlin, Lichtenstein & Langstrom, 2010). Amongst young female suicide victims, 81% have engaged in self-harm (Zahl & Hawton, 2004). Repetition of self-harm behaviour is common with repetition rates of between 10-15% within a year and up to 42% for follow-up periods longer than a year (Brent, 1997). Longitudinal studies indicate that repeated self-harm in adolescence is not only a risk factor for subsequent suicide but also carries heightened risk of psychiatric disorders into adulthood. Intervening early will benefit the young people themselves but also deliver healthcare savings. The average health service cost for an adolescent who self-harms is high at £8,058 per person per year plus £7,314 per person per year social costs. Effective treatments for adolescents who repeatedly self-harm and who are at high risk of subsequent suicide are desperately needed.

Previous studies of interventions for adolescent self-harm have rarely proved effective. One exception to this is a recently published study that applied Dialectical Behaviour Therapy (DBT), an established efficacious treatment originally developed for adult women with a history of repetitive self-harm in the context of borderline personality disorder. Mehlum and colleagues (2014), in a study conducted in Oslo, demonstrated efficacy for DBT with self-harming adolescents. In this study, parents were included in the psychoeducation component of the DBT treatment – a departure from the standard DBT protocol utilized with adults – previously described by Miller, Rathus, Linehan, Wetzler and Leigh (1997). Whilst this study is a welcome development in demonstrating that there is at least one effective intervention for repeated self-harm in adolescents, the particular protocol utilized restricts the flexibility of the intervention. Many adolescents with repeated self-harm may not live with their parents or may have highly conflicted relationships with them, which would preclude their participation in DBT for adolescents as tested by Mehlum and colleagues. Studies would indicate that adolescents not living with their family and those with high levels of family conflict may be especially vulnerable to suicidal behaviour and thus it is of concern that a potentially effective intervention would be denied them by insisting on parental participation or a particular form of parental participation. In addition, a key task of adolescence is to individuate from parents with peers as an important source of support for this process. The psychoeducation group component of DBT offers a unique opportunity for peer support in problem solving that may be inhibited for some adolescents in the presence of their parents. We, therefore, propose to further

refine and test an alternative family and carer intervention to deliver alongside DBT that will preserve the benefits of involving parents in the treatment, whilst increasing flexibility by offering support to carers other than parents, and maintain the benefit of an adolescent only psycho-educational group for skills training.

DBT was originally developed to treat women with a history of repetitive self-harm in the context of Borderline Personality Disorder (BPD). DBT is one of the most well-established treatments for this client group as indicated in a recent Cochrane Review (Stoffers et al 2013) and is also recommended by NICE (NCCMH, 2009). Following on from its promise in addressing repeated self-harm many researchers and clinicians adapted and evaluated the impact of DBT in treating adolescents with a history of self-harming (Woodberry & Popenoe, 2008). A recent meta-analysis of 19 RCTs of interventions for self-harm in adolescents has in fact indicated that DBT is the most promising intervention for this population (Ougrin, Tranah, Stahl, Moran & Asarnow, 2015).

Linehan's biosocial model of BPD conceptualises self-harming and suicidal behaviour as the result of emotion dysregulation. Emotion dysregulation refers to the inability to regulate emotions coupled with high emotional vulnerability. This means that the emotionally dysregulated individual is sensitive to emotional stimuli, experiences emotions intensely and for longer than would normally be the case. Emotion dysregulation is described by Linehan (1993) as the result of biological disposition, environmental context and the transaction between the two. Part of DBT involves providing skills for emotional modulation, however, young people are often still living in an environmental context which may continually precipitate and / or reinforce emotional dysregulation. Unlike adults, young people have little control over their environment, and studies have shown that addressing parents in family-centred intervention can bring about benefits for the whole family unit, including decreasing parental depressive symptomatology (Huey et al. 2004; Woodberry & Popenoe, 2008). Furthermore, involving the family unit is consistent with the DBT approach, as an attempt to reduce environmental pressures on the young person.

Recently, attempts have been made at providing family interventions alongside DBT for adolescents, however no family therapy model has yet been delineated for this group of young people (Miller, Glinski, Woodberry, Mitchell & Indik, 2002). Miller et al. (2002) have delineated what a potential theoretical synthesis between DBT and family therapy (FT) might look like. They indicate that the "dialectical" philosophy, which views reality as an interrelated system in continuous change is compatible with a systems perspective which views family life as composed of multiple stories and views of each family member. According to Miller et al. a DBT informed family therapy approach would take a compassionate and non-judgemental stance towards parents' experiences, validating the pain and guilt that families with problematic adolescents might be experiencing and labelling behaviours as problematic rather than families. Such an approach would ideally intervene by reducing family interactions that contribute to adolescent life-threatening behaviour, reduce parental behaviour that interferes with treatment, reduce family interactions that interfere with the families' quality of life and increase families' behavioural skills in identifying triggers and potential solutions to crisis situations.

Family Domains Therapy (FDT) was outlined by Hill, Fonagy, Safier and Sargent in 2003. It proposes a model of how problematic family interactions are constructed which allows families to reflect on how each family member expresses their needs and goes about getting their needs met. FDT highlights how there needs to be a shared understanding within a family in order for communication and actions to make sense to every family member. In other words, the family needs to be able to communicate about what their interaction is about. The experience of invalidation occurs when there is a misunderstanding between the child and the adult over what the nature of the interaction is. This misunderstanding can occur either due to a failure of the parent to understand the child's needs, or due to a confused or mixed expression of needs by the child. FDT therefore sees the experience of invalidation as emerging in interaction and takes a compassionate and non-judgemental stance towards all family members. According to FDT a "domain" is the combination of a child expressing his or her needs and the parent's response (Child's need + Parent's response = Domain). When children signal their needs clearly, and parents respond in ways that address them, the domain is referred to as being clear and matched: the parents' response matches the child's need. When domains are clear and matched, parents and children understand what is going on, and where there are problems, they know how they are to be addressed. When domains are unclear or unmatched, for example if the child is not signalling his or her needs clearly there can be misunderstandings about what is going on, and parents and children can feel angry, hurt or upset. FDT highlights four domains of interaction between parent and child based on the kind of needs the child can express and the parents' response. Three domains (attachment, safety and discipline) involve interactions that require a response from the parents; attachment involves acts of comforting, safety involves acts of protection and discipline involves acts of boundary setting and containment, in these three domains parental action is required in order to regulate the child's emotion. The fourth domain, exploration, involves an interaction which does not require parental action but interested curiosity, this kind of interaction increases shared knowledge and can occur only in a state of emotional regulation. FDT provides psychoeducation to parents regarding the impact of parenting emotionally vulnerable children and the emotional and behavioural changes that can be expected in adolescents; it informs parents of the domains approach and how this can help communication and increase parental reflective skills and capacity to identify the needs of the young person and respond coherently and consistently to those expressed needs. It helps parents manage the dialectics of safety versus attachment, safety versus discipline, attachment versus exploration, etc. FDT meets all the requirements that Miller et al (2002) have outlined as necessary to DBT informed family therapy intervention. It also addresses problems that parents of self-harming and suicidal adolescents have

identified as areas they need support in: communication and family relationships (Byrne et al., 2008).

Overall there appears to be a clear need for the development of a family therapy model consistent with the DBT approach that supports parents/carers of self-harming young people to create an environment that can accommodate the young person's emotional vulnerability and to establish whether adding family interventions to DBT augments its effectiveness. This study will assess the acceptability of Family Domains Therapy as a potential family therapy model to be used to support the parents/carers of self-harming young people alongside DBT; it will also address the practicalities of evaluating the DBT Programmes across North Wales.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

Study Aims and Predictions

This study has two parts.
PART 1 aims to assesses the feasibility, practicalities and acceptability of the recruitment and assessment procedures that would be needed to systematically assess outcome in any future RCT of DBT augmented with FDT.
PART 2 aims to assesses the uptake and acceptability of Family Domains Therapy (FDT) intervention to the parents/carers of young people undergoing the DBT programme ahead of a larger fully powered RCT. In order to determine this we will assess the percentage of parents/carers who opt into the FDT intervention, the decision making process by which parents choose to opt in or out of FDT, the perceived helpfulness and benefits of the intervention, both session-by-session and at the end of the intervention.

The main predictions of this study are:
1. We expect 50% of self-harming young people referred to CAMHS for DBT and their parents/carers to consent to participate in the research.
2. PART 1. We expect to be able to collect all the data necessary from 80% of young people who have agreed to participate in the study. This would be our criterion for feasibility. We expect measures to indicate a reduction in self-harming behaviour in the young people undergoing DBT, although, this is not a primary measure of outcome as this study is a feasibility pilot.
3. PART 2. We expect to be able to collect all the data necessary from 80% of parents/carers who have agreed to participate in the study. We expect that 50% of parents who agree to take part in the study will also opt into the FDT intervention. This would be our criterion for feasibility.
These figures have been drafted based on local clinicians' experiences of young people and parental involvement in local Child and Adolescent Mental Health Services (CAMHS).

Methodology

Design
PART 1. This part of the study answers the question:
Can data evaluating progress in treatment be systematically collected from young people in North Wales DBT programmes?
This part of the study uses a descriptive methodology involving a single group design, consisting of young people aged 14 to 18 who have been referred to DBT Programmes across North Wales. This part of the study will audit the process, feasibility and acceptability of recruiting young people to the study and collecting pre-post treatment data from questionnaires and semi-structured interviews. The data collected will concern potential outcomes, mediators and predictors of outcomes for young people undergoing DBT.
PART 2. This part of the study answers four questions:
1. How many parents/carers of young people undergoing DBT choose to take up Family Domains Therapy (FDT)?
2. Can we collect from parents/carers the data necessary to evaluate FDT?
3. How do parents/carers make the decision to opt in or out of FDT?
4. What do parents/carers find helpful about FDT?
This part of the study uses a mixed-methodology involving a single group design, consisting of the parents/carers of the young people referred for DBT.
Quantitative data will include the percentage of parents who opt into FDT and percentage of parents/carers who complete all pre- and post-treatment measures.
Qualitative data will be collected to investigate the decision-making process by which parents choose to opt in or out of FDT, and the perceived helpfulness and benefits of the intervention. This data will include a semi-structured interview, session-by-session qualitative feedback forms, and video-recordings of FDT sessions.

Participants
The study will aim to recruit 20 young people and their parents/carers from local CAMHS.

The following inclusion and exclusion criteria will be adopted when recruiting participants:
Inclusion Criteria:

Young People: -
1) The young person meets referral criteria of the DBT Programme in his/her local CAMHS (this typically includes a minimum of 5 out of 9 criteria for Borderline Personality Disorder plus self-harming behaviour).
2) The young person is aged between 14 and 18.
3) The young person is willing and able to consent to the research.
Parents/Carers:-
1) Parents and Carers of the young person who is willing and able to consent to the research.
Exclusion Criteria:

Young People: -
1) Intellectual Disability.
2) Acute Psychosis.
3) Lack of capacity to consent.
Parents/Carers:-
1) Intellectual Disability.
2) Acute Psychosis.
3) Lack of capacity to consent.

Recruitment

Young people and their parents/carers who fulfil the inclusion criteria will be identified by DBT clinicians across North Wales during their routine discussion of referrals to the DBT Programme. These perspective participants will be approached by their assigned DBT clinician during their routine initial appointment to introduce the DBT intervention. During this meeting the young person and their parents/carers will receive a brief introduction to the study and its aims, and consent to meet with the research officer, Victoria Garvey, to gain more information about the study will be sought. If they consent they will be asked to sign a consent form, highlighting that they have consented to be contacted by the research officer. Families and young people will be given an information sheet, with details of the study.

The research officer will contact the parents/carers and young people who have consented to be contacted no sooner than 24 hours after their initial meeting with the DBT clinician and will arrange to meet parents/carers and young people, together or separately as they prefer. During these meetings with the research officer, the research officer will clarify the details of the study, its aims and objectives and what is required from the participants and what the benefits and possible drawbacks for the participants might be. The parents/carers will be offered the possibility of opting into a FDT intervention and the nature of the intervention will be described and information sheets will be available should the young person or the parents/carers have misplaced those initially provided. The research officer will also explain how to contact the FDT team should parents/carers decide to take part in this intervention. Consent to participate in the study will be sought. Parents/carers will be asked to read and sign two consent forms, one to consent to being participants and one to consent to the young person's participation in the study. Young people will be provided with an assent form. Should young people or their parents/carers be undecided as to whether they wish to participate, they will be given up to 24h following the meeting with the research officer to decide.

Consent will need to be obtained from both the young person and their parents/carers in order for them both to be enrolled in the research. If consent is obtained, the research officer will send a letter to the participant's GP to inform them of the participant's involvement in the research project. Meanwhile, the research assistant, to be appointed, will schedule an appointment with the young person for the collection of the quantitative data and a separate appointment with the parents/carers in which initial data will be collected.

Study Settings

This study will take place in community CAMHS settings across Betsi Cadwaladr University Health Board.
PART 1. All data from young people will be collected in clinical rooms at the local CAMHS setting by a dedicated psychology assistant employed by BCUHB and trained in the study methodology and in the assessment tools and supervised by Dr Swales.
PART 2. Quantitative data and semi-structured interview data will either be collected at the family home or at their local CAMH service depending on parents' preference by a key researcher (Psychology Assistant or Trainee Clinical Psychologist) employed by BCUHB and trained in the assessment tools. Session-by-session qualitative rating forms and therapy session video-recordings will be collected by the BCUHB employed family therapists delivering FDT on CAMHS premises.

Safeguarding and Risk Management

Participants will be informed that should they disclose information about themselves or others being at serious risk of harm during any of the research procedures, the research team member will have to communicate that information to the young person's assigned DBT clinician and local service safeguarding procedures will be followed as stated on the participant consent forms.
There is a potential risk for researchers collecting data in family homes. Researchers going to family homes will follow local health board and service lone worker policies to ensure they log their absences from the office, and their research supervisor knows where they are, and both researcher and supervisor know emergency procedures. Parents/Carers who take part in this research will be known to services, where there are pre-existing concerns about risk to the researcher home visits for data collection will not be offered.

Ethical Considerations on Participant Information and Anonymity

Participants will be provided with an information sheet explaining the aims of the study. The information sheet will also contain contact details of the research team for any future questions they may have and provide contacts for REC members, should the participants wish to raise concerns about the conduct of the study. Participants will also be informed that the data they provide will remain anonymous and cannot be traced to their identity. The information sheet will also explain their right to withdraw at any time. Following NHS ethics guidelines, participants will also be asked to read and sign consent and assent forms.

Standard procedures to ensure the anonymity and the confidentiality of the data will be adhered to. All participants will be made aware that they may withdraw from the study at any point even after it has been completed. Participants will also be informed that their decision to withdraw at any stage of the study will not affect in any way the treatment they are receiving at their local CAMHS. Young people will all access the DBT programme as they would do ordinarily in CAMHS whether they choose to take part in the research project or not. Parents/Carers will only be able to access Family Domain Therapy (FDT) if they opt into the research, however, they will still be able to access non-specified family therapy (treatment as usual) from the same family therapists that are delivering FDT should they refuse consent to participate in this research project.

Materials and Procedure

The study consists of two parts; PART 1 addresses the feasibility and acceptability of collecting data necessary for the evaluation of Dialectical Behaviour Therapy (DBT) from young people referred to the DBT programme. This data will be collected pre-post the young person's treatment. PART 2 addresses the feasibility and acceptability of offering Family Domains Therapy (FDT), collecting the data necessary for the evaluation of FDT and exploring how parents make the choice to opt into FDT or not, and what they find helpful about it.

PART 1: YOUNG PEOPLE
Once the young person's assent to participate in the research and their parent/carer's consent has been gained, the research assistant, will arrange a meeting with the young person to complete the following assessment questionnaires and semi-structured interviews prior to the commencement of the DBT programme:

a. Borderline Symptom List-23 (Bohus et al., 2009)
The Borderline Symptom List – 23 (BSL-23) was developed as a self-rating instrument to specifically quantify borderline-typical symptomatology. The items are based on the criteria of the DSM-IV, the Diagnostic Interview for Borderline Personality Disorder – revised version, the opinions of clinical expert and borderline patients. The BSL is composed of 23 items that are rated using a 5-point scale (0=not at all, 4=very strong). The BSL has been used in recent RCT of DBT for self-harming adolescents (Mehlum et al., 2014), therefore this measure was included in this study as a potential DBT outcome measure.
b. DBT Ways of Coping Check-list (Neacsiu, Rizvi, Vitaliano, Lynch & Linehan, 2010)
The DBT Ways of Coping Check-list (DBT-WCCL) is a measure of the participant coping skills. It is a 59-item self-report scale. Each item is rated on a 4-point scale (0=never used, 3=regularly used). The DBT-WCCL is composed of two sub-scales the DBT Skills Subscale which assesses coping via the DBT skills and the Dysfunctional Coping Sub-scale (DCS) which assesses coping via dysfunctional means. It is a standard DBT outcome measure as it can successfully discriminate participants who receive skills training from those who don't. Skills training is a crucial mode of treatment in DBT and a significant moderator of symptom reduction (Neasciu et al, 2010).
c. Lifetime Parasuicide Count (Comtois & Linehan, 1999)
The Lifetime Para-suicide Count (LPC) is a semi-structured interview used to measure lifetime history of self-injurious behaviour grouped by method, intent to die, and level of medical treatment. The interview is preceded by an introduction and a definition of para-suicide. The LPC is a standard assessment measure in DBT which is routinely used with adolescent outpatients and has been recently used as assessment tool in an RCT of DBT for self-harming adolescents (Miller, Rathus & Linehan, 2007; Mehlum et al., 2014).
d. Zanarini Rating Scale for Borderline Personality Disorder (Zanarini, 2003)

The Zanarini Rating Scale for Boderline Personality Disorder (ZAN-BPD) is a brief clinician-administered interview to assess severity and change in BPD symptomatology. It has been included in this study as a potential outcome measure of DBT.

The completion of the above-mentioned measures will require approximately one to one and a half hours and might be conducted over two meetings if necessary. On all occasions the young person's assigned DBT clinician will be available to the young person following the data collection to address any distress caused by the completion of questionnaires or the semi-structured interview. The research assistant will also remind the young person that they can ask to terminate the interview at any time without having to give an explanation.

Following this initial data collection parents/carers will be invited to join their young person for a problem-solving assessment. In order to assess problem-solving the research assistant will conduct the Means Ends Problem-Solving Test (Platt & Spivak, 1975) with the young person in the presence of their parents/carers. The Means Ends Problem-Solving Test consists of 5 everyday problem-solving challenges. The young person will be asked how they might go about solving the problem and they will be oriented to discuss / seek advice from their parent/carers if they wish to do so. The interaction will be videotaped to capture their answers and the interaction with the parent. Problem-solving skills are known to be adversely affected in those who self-harm (Nock & Mendes, 2008), and for this reason DBT has a specific focus on skills training (Linehan, 1993). Thus, assessing problem-solving is a way to measure potential outcomes of DBT. Additionally, the presence of the parent/carer will allow assessment of whether and in what way the young person requests help from their parent/carer, the quality of the interaction and the level of helpfulness, all of which are potential outcomes and potential predictors of outcomes of Family Domains Therapy.

After these procedures the young person will commence the DBT Programme. When the young person comes to the end of their DBT treatment, the research assistant will arrange to meet with the young person, and measures a, b, c & d and the Means-Ends Problem-Solving test will be repeated.

PART 2A: PARENTS/CARERS

Once the parents/carers' consent to participate in the research and their consent for the young person to participate in the research is gained (Appendices 18 & 19), the research assistant will arrange a meeting with the parents/carers to complete the following assessment questionnaires:

a. General Health Questionnaire (Goldberg, 1978)

The General Health Questionnaire (GHQ) was developed as a screening instrument to identify psychological distress amongst adults in primary care settings. It is comprised of 60 self-report items on a 4-point scale (0=not at all, 3=more than usual). Research shows that parents/carers of children with behavioural problems often experience significant stress (Mouton & Tuma, 1988; Mash & Johnston, 1983; Patterson, 1982). Parent/carer mental health has been shown to be a barrier to parent/carer engagement in children's treatment (Morrissey-Kane & Prinz, 1999). The GHQ is a non-specific, broad screening tool which was included in this study as it might capture changes in various aspects of parental mental health throughout their young person's treatment and their own engagement in FDT, should they choose to engage with it.

b. Beck Depression Inventory - II (Beck, Steer & Brown, 1996)

The Beck Depression Inventory-II (BDI-II) is the most widely used tool to screen for depression in adult populations. It consists of 21 items to assess the intensity of depression in clinical and normal populations. Each item is a list of four statements arranged in increasing severity about a particular symptom of depression from which the participant must choose the one that best describes the way s/he has been feeling in the past week. The manual provides clinical cut-offs. Research suggests that parents/carers of children with behavioural problems often experience depression (Griest, Wells & Forehand, 1979; Griest & Wells, 1983), that depression can be a barrier to parental engagement and a predictor of parent/carer drop out (Morrissey-Kane & Prinz, 1999; Woodberry and Popenoe, 2008). The BDI-II was included in this study as measuring level of parent/carer depression might be beneficial to predict parental engagement and as a potential outcome measure of the young person's treatment or parents/carers' engagement in FDT.

c. SCORE-15 (Stratton et al., 2013)

The SCORE-15 Index of Family Functioning and Change is a validated self-report outcome measure designed to be sensitive to the kind of changes in family relationships that family therapists see as indications of useful therapeutic change. It is composed of 15 items and six indicators, three of them qualitative. The SCORE-15 was included in this study as potential outcome measure of FDT.

d. Appendix 9 - Parent Child Emotions and Behaviours Questionnaire

The Parent Child Emotions and Behaviours Questionnaire (PCEBQ) is a brief 10 item self-report questionnaire which asks parents/carers to rate their responses on a 5-point scale (0=never, 4=most of the time). The questionnaire was designed as an assessment and outcome tool for Family Domains Therapy (FDT) and it explores the way the parent/carer responds to the child, the parent/carer's understanding of the child's needs and the parent/carer's awareness of the way in which they communicate with their child.

e. Parent Orientation Questionnaire

The Parent Orientation Questionnaire is a brief 11 item self-report questionnaire that was designed for this study. There are 10 quantitative items which request the parent/carer to define the extent of the child's difficulties, their

perceived role in the child's recovery, parental readiness to receive help and advice and parental concern on a continuous scale (far left=not at all, far right= a lot). It also includes one open question which explores parental attributions of their child's difficulties. This scale has been devised as a potential assessment tool for Family Domains Therapy (FDT).

Each questionnaire should take no longer than five minutes to complete, overall completion of all questionnaires will require approximately 30 minutes. For each questionnaire participants will be informed that they should only proceed so long as comfortable, that they can stop the meeting at any point and that they do not have to answer every question if they do not wish to do so.

Following the completion of the questionnaires, initial qualitative data will be collected.
The research assistant will collect a Five Minute Speech Sample (Calam & Peters, 2006) of the parents describing their young person, which will be analysed to assess expressed emotion towards the young person. The same procedure will be followed at the end of the young person's treatment, with the addition of a semi-structured interview to explore how the parents/carers decided whether to opt into the FDT intervention or not, and if they have what benefits they ascribe to the treatment. The semi-structured interview should take approximately 45 minutes, bringing the end of treatment data collection meeting to approximately one hour and 15 minutes. This semi-structured interview was constructed using questions from the Change Interview (Elliott, 2008) a qualitative tool to explore post-treatment changes and from the literature on barriers to engagement in therapy (Kazdin, Holland, Crowley, & Breton, 1997)

PART 2B: PARENTS/CARERS WHO OPT FOR FAMILY DOMAIN THERAPY.
In order to explore which specific aspects of Family Domains Therapy parents/carers find useful the following qualitative data will be collected from the parents/carers who choose to undergo Family Domains Therapy. All therapy sessions will be video-recorded as this is a novel intervention. The video-recordings will be used to assist in describing the intervention in more detail for any subsequent research study, for further detailing of the Family Domains Therapy manual and in order to explore which aspects of FDT parents/carers find helpful or hindering. In order to accomplish the latter task, at the end of each therapy session the parents/carers will be asked to complete a Helpful Aspects of Therapy Form (HAT; Llewelyn, 1988) to indicate what aspects of that specific session they found helpful or unhelpful. This form should take approximately 5 minutes to complete. The use of session-by-session rating scales is routine within CAMHS settings, and associated with better outcomes in therapy. The HAT form is a qualitative post-session self-report questionnaire which uses open-ended questions to help clients write down their experiences of helpful and hindering therapy events, rate their helpfulness or unhelpfulness and indicate where in the therapy session they occurred and why they believe such events were helpful or hindering. It is a simple and efficient means of soliciting information from clients about their perceptions of key change processes in therapy. The HAT form is considered a less-intrusive and naturalistic way of collecting data, it becomes a routine part of the participants' overall therapy experiences and appears to help clients process their therapy more effectively (Elliott, 2012). The HAT's open-ended format generates qualitative data of sufficient detail and focus as to lend itself to various uses, including identification of significant events, descriptive and interpretive forms of qualitative data analysis and even quantitative content analysis (Elliott, 2012). When parent/carers near the end of their FDT treatment, the trainee clinical psychologist, Stefania Pethica, will collect all completed HAT forms and identify on video-recordings of therapy sessions the specific interactions that parents/carers have highlighted as helpful. Due to the novel nature of Family Domains Therapy, it is essential to explore what specific aspects of the therapy parents/carers find helpful in order to isolate what the change ingredients of the therapy might be, in view of developing the treatment to undergo a fully powered randomised controlled trial.

Final Debriefing
Following the data analysis a summary of main findings will be sent by post to parents/carers and young people and their views (agreement/disagreement) on such findings will be sought and integrated in the write-up of the study.

Data Analysis
PART1. This part of the study regards the feasibility and acceptability of assessing the outcomes, mediators and predictors of outcomes of DBT in North Wales. Therefore the process of recruitment, ease and acceptability of data collection is of primary interest.
Data analysis will include audit of the number of young people and their parents/carers recruited and the number of participants completing all procedures of data collection.

PART2. This part of the study regards the feasibility and acceptability of offering Family Domains Therapy to the parents/carers of the young people undergoing the DBT programme as well as the feasibility and acceptability of assessing the outcomes, mediators and predictors of outcomes of FDT. Of primary interest is the process of recruitment, ease and acceptability of data collection. Data analysis will include audit of number of parent/carers who

opt into FDT and number of parents/carers completing all procedures of data collection.

Due to the novel nature of Family Domains Therapy (FDT), this part of the research also includes the collection of qualitative data to explore how parents make the decision to opt into FDT or not and what they find helpful about FDT. Qualitative interview data collected in the final interview with both parents who have opted into FDT and those who haven't will employ a thematic analysis. Thematic analysis involves the transcription of interviews and the repeated reading of the material in order to highlight sub-themes that emerge from the text. Sub-themes are then collected into larger thematic categories that might be recurrent across several interviews with different individuals. This analysis would allow the understanding of barriers and incentives to engaging in FDT, the acceptability and feasibility of offering FDT according to parents/carers, and for those who participated in FDT the post-treatment benefits they can identify. All of this data will be essential for the future planning of a fully powered randomized controlled trial (RCT) of FDT as it will allow the prediction of potential barriers and incentives to engagement as well as the selection of outcome measures that tap into the outcomes identified by the participants.

Qualitative session-by-session data collected with the Helpful Aspects of Therapy form (HAT) will be used to guide the analysis of helpful processes that occur during the therapy itself. In the HAT form participants highlight what they have found helpful in a specific therapy session, the collection of this data allows the understanding of the immediate effects (micro-outcomes) of important moments in psychotherapy. This data will be used to conduct a quantitative content analysis of what aspects of therapy participants found helpful, it will also indicate in which therapy sessions helpful events occurred. The Trainee Clinical Psychologist, Stefania Pethica, will use the HAT form to identify the helpful event within the therapy session video recording and conduct a dialogical sequence analysis of the helpful event (Linell, 1998; Leiman, 2012). Dialogical sequence analysis involves taking topical episodes in the therapeutic conversation as focus for analysis and transcribing them for analysis. The analysis highlights aspects of the interaction, and what participants are doing in the conversation, how they position themselves towards the speaker and towards the problem being discussed. Investigating which processes parents/carers find helpful may lead to the further understanding of how the family psychotherapy process helps families make sense of their experiences and generate helpful solutions to their difficulties.

Dissemination
DBT team members meet weekly and any information requiring immediate dissemination can be fed back to participants through this route. The research assistant devoted to the project will also take responsibility for contacting participants promptly with any relevant information. The findings of this study will be used in a grant application to systematically evaluate whether FDT can augment the outcomes of DBT.
The findings of this study will also be used for a doctoral thesis by one of the key researchers, Trainee Clinical Psychologist, Stefania Pethica. Additionally, the results of this study may be published in peer-reviewed journals and presented at conferences. Participants will be given contact details for requesting a copy of the results if they so wish.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [ ] Management of the research
- [ ] Undertaking the research
- [ ] Analysis of results
- [x] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
Participant information sheets and consent forms were circulated amongst the members of the People Panel (the North Wales Clinical Psychology Programme Service User Panel). Their feedback was then incorporated in the paperwork.

Following the data analysis a summary of main findings will be sent to parents/carers and young people and their views (agreement/disagreement) on such findings will be sought and integrated in the write up of the study.
DBT team members meet weekly and any information requiring immediate dissemination can be fed through this route. The research assistant devoted to the project will also take responsibility for contacting participants promptly with any relevant information.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- ☐ Blood
- ☐ Cancer
- ☐ Cardiovascular
- ☐ Congenital Disorders
- ☐ Dementias and Neurodegenerative Diseases
- ☐ Diabetes
- ☐ Ear
- ☐ Eye
- ☐ Generic Health Relevance
- ☐ Infection
- ☐ Inflammatory and Immune System
- ☐ Injuries and Accidents
- ☑ Mental Health
- ☐ Metabolic and Endocrine
- ☐ Musculoskeletal
- ☐ Neurological
- ☐ Oral and Gastrointestinal
- ☐ Paediatrics
- ☐ Renal and Urogenital
- ☐ Reproductive Health and Childbirth
- ☐ Respiratory
- ☐ Skin
- ☐ Stroke

Gender:	Male and female participants
Lower age limit: 14	Years
Upper age limit:	No upper age limit

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

YOUNG PEOPLE RECEIVING DBT INTERVENTION.
a) the young person meets referral criteria of the DBT programme in his or her local CAMHS (this typically includes a minimum of 5 out of 9 criteria for Borderline Personality Disorder plus self-harming behaviour).
b) aged between 14 and 18.
c) willing and able to consent to the research

PARENTS/CARERS OF YOUNG PEOPLE RECEIVING DBT INTERVENTION.
a) parents and carers of the young person who is willing to consent to participate

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

YOUNG PEOPLE AND PARENTS/CARERS EXCLUSION CRITERIA:
a) intellectual disability
b) acute psychosis
c) lack capacity to consent

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Preliminary explanation and information stage - parents/carers and young people.	1	1	5 min	DBT lead when discussing DBT intervention with young person and parents/carers. To take place in a quiet room at local CAMHS.
Detailed information about the study and domains based family therapy. Parents/carers and young people.	1	n/a	30 min	Research Officer. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers. Parents/carers and young person to be seen separately if wished by young person.
General Health Questionnaire. Parents/carers only.	2	n/a	5 min	Research Assistant. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers.Delivered pre-post young person's DBT intervention.
Beck Depression Inventory - II. Parents/carers only	2	n/a	5 min	Research Assistant. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers. Delivered pre-post young person's DBT intervention.
Parent Child Emotions and Behaviours Questionniare - Parents/carers only	2	n/a	5 min	Research Assistant. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers. Delivered pre-post young person's DBT intervention.
Parent Orientation Questionnaire - parents/carers only	2	n/a	5 min	Research Assistant. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers.Delivered pre-post young person's DBT intervention.
SCORE-15 - parents/carers only	1	n/a	5min	Research Assistant. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers.Delivered pre-post young person's DBT intervention.
5 minute speech sample describing young person - parents/carers only	2	n/a	5 min	Research Assistant. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers. One speech sample collected at beginning of research one collected after young person has completed DBT intervention.
Lifetime parasuicide count, semi-structured interview - young person only	2	2	30 min	Research assistant. To take place in a quiet room at local CAMHS. (During this appointment the measures below will also be taken: Borderline symptom checklist-23, Zanarini rating scale)
DBT Ways of coping checklist - young person only	2	2	5 min	Research assistant. To take place in a quiet room at local CAMHS.
Borderline symptom list 23 - young person only	2	2	5 min	Research assistant. To take place in a quiet room at local CAMHS.
Zanarini rating scale for borderline personality disorder -	2	n/a	30 min	Research assistant. To take place in a quiet room at local CAMHS.

young person only				
Means End Problem Solving Task - young person and parent/carers	2	n/a	30 min	Research assistant. To take place in a quiet room at local CAMHS.
Feedback to young people and parents/carers	1	n/a	5 min	Information about outcome and request of young person's and parent/carers's opinion of findings sent by post with enclosed return envelope included.
Interview on the decision to opt in or out of FDT and its benefits	1	n/a	45min	Research Assistant or Trainee Clinical Psychologist. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers.Delivered pre-post young person's DBT intervention.
Helpful Aspects of Therapy Form	1	n/a	5min	This form is a session-by-session rating form will be collected at the end of each FDT therapy session. It will be collected by the family therapist delivering the intervention. Parents/Carers will complete as many as number of sessions they undergo.

A19. Give details of any clinical intervention(s) or procedure(s) to be received by participants as part of the research protocol. *These include uses of medicinal products or devices, other medical treatments or assessments, mental health interventions, imaging investigations and taking samples of human biological material. Include procedures which might be received as routine clinical care outside of the research.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days).
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Standard DBT intervention for young people with emerging borderline personality disorder - individual therapy	20	20	1 hour	Assigned local CAMHS clinician. Intervention will take place at local CAMHS.
Standard DBT intervention for young people with emerging borderline personality disorder - skills training group	22	22	2 hours	Assigned local CAMHS clinician. Intervention will take place at local CAMHS.
Family Domains Therapy intervention for parents/carers	10	n/a	1 hour	Local CAMHS Family therapist. Intervention will take place at local CAMHS. Total number of interventions will depend on family functioning, an estimate of eight sessions per family will be provided. However should families need more sessions they will be provided in accordance with the family's needs.

A20. Will you withhold an intervention or procedure, which would normally be considered a part of routine care?

○ Yes ◉ No

A21. How long do you expect each participant to be in the study in total?

Participants are expected to remain in the study for approximately the length of the standard DBT intervention, which is 20 to 24 weeks.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

For the young people participating in the research will involve completing additional questionnaires and semi-structured interviews which address potentially distressing experiences. The research assistant delivering the intervention will be trained to interrupt the data collection should the participant become distressed. The research assistant will also encourage participants to proceed with the interviews as they feel comfortable and to cease involvement at their own discretion. In addition the young person's assigned clinician will be available following the data collection to discuss any issues raised during the data collection for the participant. It is also part of standard DBT intervention for young people to have their clinician's telephone number to contact if they become unduly distressed during the week.

For the parents/carers, the study involves the completion of questionnaires, providing a speech sample and a follow up interview on decision making process to opt in or out of the family domains therapy intervention and its benefits. Careful instructions and reassurance have been factored into the request for a speech sample, assuring participants to only proceed as they feel comfortable, and to cease involvement at their own discretion. Parents/carers who opt into family domains therapy will potentially experience distress connected with discussing difficult family interactions, this however will be no different than in any other family intervention. All family therapists delivering FDT are experienced in delivering family therapy interventions and supporting parents/carers throughout.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

(●) Yes ( ) No

If Yes, please give details of procedures in place to deal with these issues:

Local health board and service procedures will be followed. If a disclosure occurs:
1. the participant will be reminded of the content of the consent forms and the limits of service confidentiality.
2. the research team member conducting the interview or questionnaire will then proceed by contacting the young person/parent/carer's assigned clinician.
Researcher's behaviour in the face of disclosure has been outlined in both Participant Information Sheets and Consent Forms.

A24. What is the potential for benefit to research participants?

Participation in this study will benefit participants in the following ways:
1) for young people and their parents/carers it will provide an opportunity to make a contribution to research.
2) for parents/carers this research will provide the opportunity to discuss their experience of their young person's behaviour, receive a novel family therapy intervention and to participate in shaping a form of therapy.

A25. What arrangements are being made for continued provision of the intervention for participants, if appropriate, once the research has finished? *May apply to any clinical intervention, including a drug, medical device, mental health intervention, complementary therapy, physiotherapy, dietary manipulation, lifestyle change, etc.*

Young people will receive standard follow up from the DBT intervention as provided by their local services.

Parents/carers receiving FDT intervention will be followed up by their family therapist. The family therapist will consider continuing to offer FDT depending on the feasibility/acceptability of this therapy model highlighted by the research itself. Supportive family therapy will also be available to families at end of the research study in line with the families needs and wishes.

A26. What are the potential risks for the researchers themselves? *(if any)*

There is a potential risk for researchers conducting semi-structured interviews/questionnaires in family homes. Researchers going to family homes will follow local health board lone worker policy to ensure they log their absences from the office, and their research supervisor knows where they are, and researchers know emergency procedure. Families who take part in this research project will be known to services, where there are concerns about risk to the researchers clinic meetings only will be offered.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

Participants will only be identified by local CAMHS care teams. This process will take place during the course of their normal screening of referrals for DBT.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

(•) Yes ( ) No

Please give details below:
Participants will only be identified by local CAMHS care teams. This process will take place during the course of their normal screening of referrals for DBT. Researchers will have access to demographic information and will have access to parents/carers' contact details only with participant consent .

A27-3. Describe what measures will be taken to ensure there is no breach of any duty of confidentiality owed to patients, service users or any other person in the process of identifying potential participants.*Indicate what steps have been or will be taken to inform patients and service users of the potential use of their records for this purpose. Describe the arrangements to ensure that the wishes of patients and service users regarding access to their records are respected. Please consult the guidance notes on this topic.*

All identifiable information will be stored safely in locked metal filing cabinets in local CAMHS. Researchers will only have access to demographic information and contact details with participant consent.

A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

(•) Yes ( ) No

A27-5. Has prior consent been obtained or will it be obtained for access to identifiable personal information?

(•) Yes ( ) No

If Yes, please give details below.
Consent to access identifiable personal information, such as contact details, will be obtained by the research assistant in writing as part of the consent to participate in the research project (see Consent to be contacted by researcher forms and consent forms).

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

( ) Yes (•) No

A29. How and by whom will potential participants first be approached?

Participants will be approached by direct care team (DBT clinical lead) as part of routine meeting following referral for DBT intervention for the young person.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

At the initial routine meeting with the DBT clinical lead participants will be provided with a consent form requesting their consent to be contacted by the research officer, together with a brief verbal explanation detailing the purpose and background to the study, and what they will be required to do if taking part. At this stage young people and their parents/carers will be asked to provide written consent to be contacted by the research officer Victoria Garvey and will be provided with an information sheet about the study.

Following the receipt of detailed information the research officer will meet with the parents and carers and young people to discuss the research in more detail and answer any questions that they may have. Young people and their parents / carers will be given the opportunity to opt into the research project. Young people will be asked to sign an assent form, and parents/carers will be asked to sign a participant consent form and a consent form for the young person to participate in the research project. It will be made clear to parents/carers that if they do not opt into the research they will still be able to access other family support offered by CAMHS and to young people that they can access DBT whether or not they consent to research participation. Only when consent to participate in the research is obtained from both parents/carers and the young person will they be enrolled into the study.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◉ Yes ○ No

A31. How long will you allow potential participants to decide whether or not to take part?

During the meeting with the research officer prospective participants might decide to opt in or out of the research or request more time to consider whether they would like to participate. If they request more time they will be given 24h to consider whether they would like to take part in the research project and asked to sign the parent/carer as participant consent form, the parent/carer as guardian consent form and the young person's assent form.

A32. Will you recruit any participants who are involved in current research or have recently been involved in any research prior to recruitment?

○ Yes
◉ No
○ Not Known

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

The nature of some of the tasks included in the study requires a good level of English comprehension, and therefore individuals who do not fulfil this c riteria will not be recruited for the study. This is to both pr eserve the integrity of the data produced, and to prevent wasting the time of and/or causing undue stress or embarrassment to individuals without the required level of English comprehension for the tasks at hand.

A33-2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to participants in Wales?

All consent and information forms will be translated into Welsh.
However, Welsh speaking participants will be informed that data analysis will be conducted in English, thus individuals who would wish to participate in research interviews through the medium of Welsh will not be included in the study.
Welsh speaking participants who chose to opt in will have the opportunity of receiving the clinical interventions (DBT, FDT) through the medium of Welsh in some areas but would need to consent to conducting the research interview through the medium of English.
However, the decision not to participate in the research interviews would not preclude any family or young person from accessing treatment as usual.

A34. What arrangements will you make to ensure participants receive any information that becomes available during the course of the research that may be relevant to their continued participation?

DBT team members meet weekly and any information requiring immediate dissemination can be fed through this route. The Research Assistant devoted to the project will also take responsibility for contacting participants promptly with any relevant information.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

- ○ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- ◉ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- ○ The participant would continue to be included in the study.
- ○ Not applicable – informed consent will not be sought from any participants in this research.
- ○ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?*(Tick as appropriate)*

- ☐ Access to medical records by those outside the direct healthcare team
- ☐ Access to social care records by those outside the direct social care team
- ☐ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA

- [x] Use of personal addresses, postcodes, faxes, emails or telephone numbers
- [x] Publication of direct quotations from respondents
- [ ] Publication of data that might allow identification of individuals
- [x] Use of audio/visual recording devices
- [x] Storage of personal data on any of the following:
  - [x] Manual files (includes paper or film)
  - [x] NHS computers
  - [ ] Social Care Service computers
  - [ ] Home or other personal computers
  - [x] University computers
  - [ ] Private company computers
  - [x] Laptop computers

Further details:
All participants will be allocated an identifying code unique to them.
All experimental materials will only use this code for id entification, no other details leading to identification will be recorded on such materials.
Codes will be stored separately from personal identifying information.

A37. Please describe the physical security arrangements for storage of personal data during the study?

All data in paper format will be held in securely locked metal filing cabinets in the office of the Chief Investigator (Dr Michaela Swales).

All data in digital form (qualitative data recordings, anonymized quantitative data, anonymized qualitative data transcripts) will be held either on encrypted USB sticks or on the BCUHB secure network drive, accessed by a BCUHB laptop which will also be encrypted. All digital data will be held in password protected folders. All laptops used will be password protected, no data will be stored on computer hard drives.

An audio recording device will be used to collect qualitative data and will be stored in a securely locked metal filing cabinet in the office of Dr Swales. Following each interview mp3 files of the qualitative data will be moved from the recording device to an encrypted USB stick in a password protected file and permanently deleted from the audio recording device. The same procedure will be followed for video files.

Any video-recording devices employed will be property of BCUHB. Each family therapist and the research assistant will be assigned a video-recording device, these will be stored in a securely locked metal filing cabinet in their offices on BCUHB premises. Following each session video files of the qualitative data will be moved from the recording device to a password protected BCUHB computer in a password protected file and permanently deleted from the video recording device. The Trainee Clinical Psychologist will access video-files on BCUHB premises using BCUHB computers for qualitative data analysis.

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

An anonymous ID code will be assigned to each participant and use d as the only
identifier in all experimental materials.
The data produced by the study w ill only contain the anonymous identifier codes,
and all work done on the data w ill use those codes only.
The master list of personal contact d etails that links to the anonymous ID
codes will be kept separa te and securely locked away from all other materials in the offic e of the Chief Investigator (Dr Michaela Swales).
Where direct quotes of participants will be used a pseudonym will be assigned to each participant.
The research team will only have access to demographic data and the personal data that allows them to contact the participants in order to schedule appointments for interviews/data collection.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

Only the research team will have access to participants' personal data during the study.
Personal data will be kept securely and separate from all other research data
and only used when required to fulfil the ethical obligations of the study and to contact participants to arrange appointments for data collection.
All necessary work will be carried out with anonymised data which will not be
traceable to any individual personal data.
Video and audio recordings will be accessed by researchers on BCUHB premises.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

Data generated will be analysed by the Research Assistant and Trainee Clinical Psychologist. Anonymised data analysis will be conducted on BCUHB premises.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title Forename/Initials Surname
	Dr Michaela Swales
Post	Consultant Clinical Psychologist & Senior Lecturer
Qualifications	PhD: Psychological processes of change in adolescents in a residential setting MPhil: Psychopathology MPhil: History & Philosophy of Science BA (Hons): Natural Science British Psychological Society: Diploma of Clinical Psychology
Work Address	North Wales Clinical Psychology Programme Bangor University Bangor, Gwynedd
Post Code	LL57 2DG
Work Email	m.swales@bangor.ac.uk
Work Telephone	
Fax	

A43. How long will personal data be stored or accessed after the study has ended?

- ○ Less than 3 months
- ◉ 3 – 6 months
- ○ 6 – 12 months
- ○ 12 months – 3 years
- ○ Over 3 years

A44. For how long will you store research data generated by the study?

Years: 7
Months:

A45. Please give details of the long term arrangements for storage of research data after the study has ended. *Say where data will be stored, who will have access and the arrangements to ensure security.*

Digital data will be stored on encrypted USB in password protected file, and paper data will be stored in securely locked metal filing cabinet together with USB. These will be stored in the office of Research Supervisor Dr Michaela Swales.
Anonymized data (such as anonymized quantiative data or anonymized qualitative transcripts) could be made accessible to Trainee Clinical Psychologists for the analysis of family functioning or to conduct Service Related Research Projects in the future. Consent for use of anonymized data in future research will be sought from participants and will be included in the consent forms.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

○ Yes ◉ No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

◉ Yes ○ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

A49-2. Will you seek permission from the research participants to inform their GP or other health/ care professional?

◉ Yes ○ No

It should be made clear in the participant's information sheet if the GP/health professional will be informed.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

The Department of Health's Research Governance Framework for Health and Social Care and the research governance frameworks for Wales, Scotland and Northern Ireland set out the requirement for registration of trials. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has

been registered in an appropriate registry. Please see guidance for more information.

○ Yes ◉ No

Please give details, or justify if not registering the research.
The research will not be registered as it is a feasibility study and will not have the design or statistical power of a randomised control trial.

Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- ☑ Peer reviewed scientific journals
- ☐ Internal report
- ☑ Conference presentation
- ☐ Publication on website
- ☐ Other publication
- ☐ Submission to regulatory authorities
- ☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- ☐ No plans to report or disseminate the results
- ☑ Other (please specify)

Part of the results of the study will be used for a Doctoral Thesis in Clinical Psychology by Trainee Clinical Psychologist Stefania Pethica.

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

No identifiable personal data will be published. If quotes from qualitative analysis are to be used the participants will be given pseudonyms. All identifiable information will be removed from transcripts of interviews prior to publication of quotes.

A53. Will you inform participants of the results?

◉ Yes ○ No

Please give details of how you will inform participants or justify if not doing so.
All participants will receive a document through the post outlining the main findings of the study, and participants will be asked for their feedback on the findings (agreement/disagreement). A return envelope will be present in the document.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- ☐ Independent external review
- ☐ Review within a company
- ☑ Review within a multi−centre research group
- ☑ Review within the Chief Investigator's institution or host organisation
- ☑ Review within the research team
- ☑ Review by educational supervisor
- ☐ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
This proposal has been produced by key researcher Stefania Pethica. The study development process has consisted of regular meetings between the Trainee Clinical Psychologist (Stefania Pethica), the Chief Investigator, the Research Assistant and other members of the clinical team delivering the domains based family therapy intervention, involving the close scrutiny of all relevant details to create a well thought through proposal. The outcome of this careful review of the study proposal is a clearly identified research question, a structured plan for completing the research, and a design that has sought to protect the welfare of participants and reduce the burden on participants at every stage.

The proposal has also been reviewed by Dr Mike Jackson(Bangor Unviersity Research Team for the North Wales Clinical Psychology Programme). The outline proposal was also reviewed by the Pathway to Portfolio Grant Awarding Committee in BCUHB that is funding the project.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

- ☐ Review by independent statistician commissioned by funder or sponsor
- ☐ Other review by independent statistician
- ☐ Review by company statistician
- ☐ Review by a statistician within the Chief Investigator's institution
- ☐ Review by a statistician within the research team or multi−centre group
- ☑ Review by educational supervisor
- ☐ Other review by individual with relevant statistical expertise
- ☑ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

Title Forename/Initials Surname

Department
Institution
Work Address

Post Code
Telephone
Fax
Mobile
E-mail

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

The primary outcome of the study will be the percentage of young people and parent/carers consented who complete all the measures. The percentage of parents/carers who opt into the FDT intervention. This is a study on the feasibility and acceptability of assessing the outcomes, mediators and predictors of outcomes of FDT and DBT in North Wales. Therefore our interest is in the process of recruitment, ease and acceptability of data collection.

Criteria for feasibility are the following:
-50% of young people and their parent/carers approached agree to take part in the study.
-all data is collected from 80% of participants.
-50% of parents/carers recruited agree to undertake FDT.

Qualitative analysis will be conducted on parent/carer end of treatment interview, session-by-session rating forms and session video recordings which will produce information about what parents/carers find helpful about FDT, and acceptability of FDT.

A58. What are the secondary outcome measures? *(if any)*

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:	20
Total international sample size (including UK):	0
Total in European Economic Area:	0

Further details:
The participants will be young people aged 14 to 17 referred to CAMHS for DBT intervention. And their parents/carers.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

The sample size was decided based on the current levels of referrals to CAMHS for DBT interventions and an estimation of how many referred individuals will accept to take part in the study based on clinical experience.

A61. Will participants be allocated to groups at random?

○ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

1. Audit of number of young people and their parents/carers recruited, number of parents/carers opting into FDT, and number of participants completing all procedures of data collection.
2. Thematic analysis, content analysis and dialogical sequence analysis of qualitative data.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title Forename/Initials Surname
	Prof Jonathan Hill
Post	Professor of Child and Adolescent Psychiatry
	University 1968-1971 Tripos Exams Sidney Sussex College Cambridge Natural Sciences Pt. 1a Medical Sciences Pt. 1a Pt. 1b (Including Experimental Psychology) 1971 B.A. Class 2.1

	Clinical Training 1971-1974 St. Thomas Hospital, London Haematology Prize 1974 M.B. B.Chir.
Qualifications	General Training in Psychiatry – Maudsley Hospital, London 1979 M.R.C.Psych. 1998 F.R.C.Psych. Senior Registrar Training Scheme in Child Psychiatry, Maudsley Hospital, London Research Training 1984 - 1986 M.R.C. Training Fellowship in the Department of Child and Adolescent Psychiatry, Institute of Psychiatry, London. Supervisor: Professor M Rutter.
Employer	Reading University
Work Address	School of Psychology and Clinical Language Sciences University of Reading, Earley Gate, Reading
Post Code	RG6 6AL
Telephone	
Fax	
Mobile	
Work Email	j.hill@reading.ac.uk

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status: (•) NHS or HSC care organisation
( ) Academic
( ) Pharmaceutical industry
( ) Medical device industry
( ) Local Authority
( ) Other social care provider (including voluntary sector or private organisation)
( ) Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation	Bangor University School of Psychology
Given name	Hefin
Family name	Francis
Address	School of Psychology Adeilad Brigantia
Town/city	Penrallt Road Gwynedd
Post code	LL57 2AS
Country	UNITED KINGDOM
Telephone	+44 (0) 1248 388339
Fax	+44 (0) 1248 38 2599

E-mail h.francis@bangor.ac.uk

Is the sponsor based outside the UK?

◯ Yes ◉ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

☑ Funding secured from one or more funders

☐ External funding application to one or more funders in progress

☐ No application for external funding will be made

What type of research project is this?

◉ Standalone project

◯ Project that is part of a programme grant

◯ Project that is part of a Centre grant

◯ Project that is part of a fellowship/ personal award/ research training award

◯ Other

Other – please state:

Please give details of funding applications.

Organisation	BCUHB
Address	R&D Office, Clinical School Ysbyty Gwynedd Penrhosgarnedd BANGOR
Post Code	LL57 2PW
Telephone	01248384384
Fax	
Mobile	
Email	Rossela.Roberts@wales.nhs.uk

Funding Application Status: ◉ Secured ◯ In progress

Amount: 38,456

Duration

Years: 2

Months:

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?

Pathway to Portfolio (P2P)

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

○ Yes ◉ No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

○ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	Dr	Nefyn	Williams
Organisation	Betsi Cadwaladr University Health Board		
Address	Clinical Academic Office		
	Ysbyty Gwynedd		
	Bangor		
Post Code	LL57 2PW		
Work Email	nefyn.williams@bangor.ac.uk		
Telephone	01248384877		
Fax			
Mobile			

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/01/2016
Planned end date: 31/03/2017
Total duration:
Years: 1 Months: 2 Days: 31

A71-1. Is this study?

◉ Single centre
○ Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

☐ England
☐ Scotland
☑ Wales
☐ Northern Ireland
☐ Other countries in European Economic Area

Total UK sites in study 1

Does this trial involve countries outside the EU?

○ Yes ◉ No

A72. Which organisations in the UK will host the research? *Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

☐ NHS organisations in England	
☑ NHS organisations in Wales	1
☐ NHS organisations in Scotland	
☐ HSC organisations in Northern Ireland	
☐ GP practices in England	
☐ GP practices in Wales	
☐ GP practices in Scotland	
☐ GP practices in Northern Ireland	
☐ Joint health and social care agencies (eg community mental health teams)	
☐ Local authorities	
☐ Phase 1 trial units	
☐ Prison establishments	
☐ Probation areas	
☐ Independent (private or voluntary sector) organisations	
☐ Educational establishments	
☐ Independent research units	
☐ Other (give details)	
Total UK sites in study:	1

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

○ Yes ◉ No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

The Trainee Clinical Psychologist, Research Officer and Research Assistant will be supervised regularly by Dr Swales. DBT therapists and Family therapists will also have weekly meeting to discuss outcomes and risk management.

A75-1. What arrangements will be made to review interim safety and efficacy data from the trial? Will a formal data monitoring committee or equivalent body be convened?

No DMEC. DBT therapists and Family therapists will also have weekly meeting to discuss outcomes and risk management.

If a formal DMC is to be convened, please forward details of the membership and standard operating procedures to the Research Ethics Committee when available. The REC should also be notified of DMC recommendations and receive summary reports of interim analyses.

A75-2. What are the criteria for electively stopping the trial or other research prematurely?

Not applicable, as all additionally provided interventions (FDT) in this study will be provided according to participants needs and wishes. Participants will be informed that they can interrupt interviews for data collection should they wish to and this will not have an impact on their treatment.

A76. Insurance/ indemnity to meet potential legal liabilities

Note: in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

- ☐ NHS indemnity scheme will apply (NHS sponsors only)
- ☑ Other insurance or indemnity arrangements will apply (give details below)

Bangor University Indemnity scheme will apply.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

- ☑ NHS indemnity scheme will apply (protocol authors with NHS contracts only)
- ☐ Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

- ☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
- ☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

A77. Has the sponsor(s) made arrangements for payment of compensation in the event of harm to the research participants where no legal liability arises?

○ Yes ◉ No

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

○ Yes ○ No ◉ Not sure

PART B: Section 7 - Children

1. Please specify the potential age range of children under 16 who will be included and give reasons for carrying out the research in this age group.

Young people with self-harming behaviour aged 14 to 18 referred to CAMHS for a DBT intervention will be included in the study.Self-harm includes any act of intentional self-poisoning or self-injury regardless of motivation and, therefore, includes acts with suicidal intent and those without. Self-harm in adolescence is a major public health problem. The behaviour is highly prevalent (occurring in about 10% of adolescents), often repeated and is the strongest predictor of subsequent suicide. Self-harm exacts a distressing toll on young people and their families and is expensive in terms of health and social costs. Young people with repetitive self-harm often fail to achieve in education and go on to have persistent mental health problems.

Suicide is the second most common cause of death in adolescence (Patton et al., 2009). Increased severity of self-harm is associated with higher levels of depression, anxiety and impulsivity (Madge et al., 2011), and patients who escalate their severity of self-harm are at high risk of completed suicide (Carter, Reith, Whyte & McPherson, 2005). Strangulation and attempted hanging in adolescents have increased, both of which are strongly associated with completed suicide (Runeson, Tidemalm, Dahlin, Lichtenstein & Langstrom, 2010). Amongst young female suicide victims, 81% have engaged in self-harm (Zahl & Hawton, 2004). Repetition of self-harm behaviour is common with repetition rates of between 10-15% within a year and up to 42% for follow-up periods longer than a year (Brent, 1997). Longitudinal studies indicate that repeated self-harm in adolescence is not only a risk factor for subsequent suicide but also carries heightened risk of psychiatric disorders into adulthood. Intervening early will benefit the young people themselves but also deliver healthcare savings. The average health service cost for adolescent who self-harm is high at £8,058 per person per year plus £7,314 per person per year social costs. Effective treatments for adolescents who repeatedly self-harm and who are at high risk of subsequent suicide are desperately needed.

Previous studies of interventions for adolescent self-harm have rarely proved effective. One exception to this is a recently published study that applied Dialectical Behaviour Therapy (DBT) an established as efficacious treatment originally developed for adult women with a history of repetitive self-harm in the context of borderline personality disorder. Mehlum and colleagues (2014), in a study conducted in Oslo, demonstrated efficacy for DBT with for self-harming adolescents. In this study, parents were included in the psychoeducation component of the DBT treatment – a departure from the standard DBT protocol utilized with adults - previously described by Miller, Rathus, Linehan, Wetzler and Leigh (1997). Whilst this study is a welcome development in demonstrating that there is at least one effective intervention for repeated self-harm in adolescents, the particular protocol utilized restricts the flexibility of the intervention. Many adolescents with repeated self-harm may not live with their parents or may have highly conflicted relationships with them, which would preclude their participation in DBT for adolescents as tested by Mehlum and colleagues. Studies would indicate that adolescents not living with their family and those with high levels of family conflict may be especially vulnerable to suicidal behaviour and thus it is of concern that a potentially effective intervention would be denied them by insisting on parental participation or a particular form of parental participation. In addition, a key task of adolescence is to individuate from parents with peers as an important source of support for this process. The psychoeducation group component of DBT offers a unique opportunity for peer support in problem solving that may be inhibited for some adolescents in the presence of their parents. We, therefore, propose to further refine and test an alternative family & carer intervention to deliver alongside DBT that will preserve the benefits of involving parents in the treatment, whilst increasing flexibility by offering support to carers other than parents, and maintain the benefit of an adolescent only psycho-educational group for skills training.

DBT was originally developed to treat women with a history of repetitive self-harm in the context of Borderline Personality Disorder (BPD). DBT is one of the most well-established treatments for this client group as indicated in a recent Cochrane Review (Stoffers et al 2013) and is also recommended by NICE (NCCMH, 2009). Following on from its promise in addressing repeated self-harm many researchers and clinicians adapted and evaluated the impact of DBT in treating adolescents with a history of self-harming (Woodberry & Popenoe, 2008). A recent meta-

analysis of 19 RCTs of interventions for self-harm in adolescents has in fact indicated that DBT is the most promising intervention for this population (Ougrin, Tranah, Stahl, Moran & Asarnow, 2015).

Linehan's biosocial model of BPD conceptualises self-harming and suicidal behaviour as the result of emotion dysregulation. Emotion dysregulation refers to the inability to regulate emotions coupled with high emotional vulnerability. This means that the emotionally dysregulated individual is sensitive to emotional stimuli, experiences emotions intensely and for a longer period of time. Emotion dysregulation is described by Linehan (1993) as the result of biological disposition, environmental context and the transaction between the two. Part of DBT involves providing skills for emotional modulation, however, young people are often still living in an environmental context which may continually precipitate and / or reinforce emotional dysregulation. Unlike adults, young people have little control over their environment, and studies have shown that addressing parents in family-centred intervention can bring about benefits for the whole family unit, including decreasing parental depressive symptomatology (Huey et al. 2004; Woodberry & Popenoe, 2008). Furthermore, involving the family unit is consistent with the DBT approach, as an attempt to reduce environmental pressures on the young person.

Recently, attempts have been made at providing family interventions alongside DBT for adolescents, however no family therapy model has yet been delineated for this group of young people (Miller, Glinski, Woodberry, Mitchell & Indik, 2002). Miller et al. (2002) have delineated what a potential theoretical synthesis between DBT and family therapy might look like. They indicate that the "dialectical" philosophy, which views reality as an interrelated system in continuous change is compatible with a systems perspective which views family life as composed of multiple stories and views of each family member. According to Miller et al. a DBT informed family therapy approach would take a compassionate and non-pejorative stance towards parents' experiences, validating the pain and guilt that families with problematic adolescents might be experiencing and labelling behaviours as problematic rather than families. Such an approach would ideally intervene by reducing family interactions that contribute to adolescent life-threatening behaviour, reduce parental behaviour that interferes with treatment, reduce family interactions that interfere with families' quality of life and increase families' behavioural skill in identifying triggers and potential solutions to crisis situations.

2. Indicate whether any children under 16 will be recruited as controls and give further details.

No, all young people (14 to 18) will receive active treatment.

3-2. Please describe the arrangements for seeking informed consent from a person with parental responsibility and/or from children able to give consent for themselves.

In the first meeting between the care team (assigned DBT clinician) and the young person and their parents/carers, the information about the research project will be shared.
Consent in writing to be contacted by the research officer to gain more information about the research project will be sought from both parents/carers and the young person. Where both the parents/carers and young person consent to be contacted by the research officer each will be given an information sheet with details of the aims of the study, what the potential benefits and drawbacks are for participants. Following this the research officer will meet with parents/carers and the young person individually and seek consent to participate in the research. Only where both parents/carers and young person consent to participate in the research will the family be enrolled in the study.

4. If you intend to provide children under 16 with information about the research and seek their consent or agreement, please outline how this process will vary according to their age and level of understanding.

The information will be provided by the care team (DBT lead clinician) and the Research Officer in a way that is appropriate to the young person's understanding. An information sheet tailored to young people and what the research project requires of them will be used.
Parents/carers will also be informed in the initial meeting with the assigned DBT clinician and consent forms and explanatory information will also be provided for them.

Copies of written information sheet(s) for parents and children, consent/assent form(s) and any other explanatory material should be enclosed with the application.

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.*

Research site		Investigator/ Collaborator/ Contact	
Institution name	Betsi Cadwaladr University Health Board Trust	Title	Dr
Department name	Child and Adolescent Mental Health Services	First name/ Initials	Michaela
Street address	Croesnewydd Rd	Surname	Swales
Town/city	Wrexham		
Post Code	LL13 7TD		

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.
9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.
10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
11. I understand that the main REC or its operational managers may share information in this application or supporting documentation with the Medicines and Healthcare products Regulatory Agency (MHRA) where it is relevant to the Agency's statutory responsibilities.
12. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

- ◯ Chief Investigator
- ◯ Sponsor
- ◯ Study co-ordinator
- ◯ Student
- ◯ Other – please give details
- ◯ None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☐ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Dr Michaela Swales on 04/01/2016 19:37.

Job Title/Post:	Consultant Psychologist
Organisation:	BCUHB
Email:	m.swales@bangor.ac.uk

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by Mr Hefin Francis on 05/01/2016 14:44.

Job Title/Post:	School Manager for Psychology
Organisation:	Bangor University
Email:	h.francis@bangor.ac.uk

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by Dr Mike Jackson on 05/01/2016 10:55.

Job Title/Post:	clinical psychologist
Organisation:	bcuhb
Email:	mike.jackson@wales.nhs.uk

Academic supervisor 2

This section was signed electronically by Dr Michaela Swales on 04/01/2016 19:36.

Job Title/Post:	Consultant Psychologist
Organisation:	BCUHB
Email:	m.swales@bangor.ac.uk

ETHICS APPENDIX IX

NHS Site Specific Information Form

NHS SSI

IRAS Version 5.2.0

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Feasibility of offering family domains therapy alongside DBT

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product

( ) Clinical investigation or other study of a medical device

( ) Combined trial of an investigational medicinal product and an investigational medical device

(●) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

( ) Study limited to working with data (specific project only)

( ) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?

( ) Yes (●) No

2b. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation? ( ) Yes (●) No

b) Will you be taking new human tissue samples (or other human biological samples)? ( ) Yes (●) No

c) Will you be using existing human tissue samples (or other human biological samples)? ( ) Yes (●) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

- [ ] England
- [ ] Scotland
- [x] Wales
- [ ] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- ○ England
- ○ Scotland
- ◉ Wales
- ○ Northern Ireland
- ○ This study does not involve the NHS

4. Which review bodies are you applying to?

- [ ] HRA Approval
- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] Research Ethics Committee
- [ ] Confidentiality Advisory Group (CAG)
- [ ] National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

◉ Yes ○ No

6. Do you plan to include any participants who are children?

◉ Yes ○ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

(●) Yes ( ) No

Please describe briefly the involvement of the student(s):
Doctoral Clinical Psychology Trainee to analyse qualitative data.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

(●) Yes ( ) No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

( ) Yes (●) No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

( ) Yes (●) No

Site-Specific Information Form (NHS sites)

Is the site hosting this research a NHS site or a non-NHS site? *NHS sites include Health and Social Care organisations in Northern Ireland. The sites hosting the research are the sites in which or through which research procedures are conducted. For NHS sites, this includes sites where NHS staff are participants.*

- (●) NHS site
- ( ) Non-NHS site

This question must be completed before proceeding. The filter will customise the form, disabling questions which are not relevant to this application.

One Site-Specific Information Form should be completed for each research site and submitted to the relevant R&D office with the documents in the checklist. See guidance notes.

The data in this box is populated from Part A:

Title of research:
A feasibility study investigating the provision of a Family Domains Therapy (FDT) intervention for the parents/carers of self-harming young people undergoing Dialectical Behaviour Therapy (DBT) in North Wales

Short title: Feasibility of offering family domains therapy alongside DBT

Chief Investigator:	Title	Forename/Initials	Surname
	Dr	Michaela	Swales

Name of NHS Research Ethics Committee to which application for ethical review is being made:
Wales REC 5

Project reference number from above REC: 16/WA/0025

1-1. Give the name of the NHS organisation responsible for this research site

Betsi Cadwaladr University Health Board

1-3. In which country is the research site located?

- ( ) England
- (●) Wales
- ( ) Scotland
- ( ) Northern Ireland

1-4. Is the research site a GP practice or other Primary Care Organisation?

( ) Yes (●) No

2. Who is the Principal Investigator or Local Collaborator for this research at this site?

Select the appropriate title: (●) Principal Investigator ( ) Local Collaborator

	Title	Forename/Initials	Surname
	Dr	Michaela	Swales
Post	Consultant Clinical Psychologist & Senior Lecturer and Academic Lead for CAMHS		
Qualifications	BA (Hons), MPhil, MPhil, PhD		
Organisation	Betsi Cadwaladr University Health Board & North Wales Clinical Psychology Programme, School of Psychology, Bangor University		
Work Address	North Wales Clinical Psychology Programme		
	Bangor University		
	Bangor, Gwynedd		
PostCode	LL57 2DG		
Work E-mail	Michaela.Swales@bangor.ac.uk		
Work Telephone	01248 382552		
Mobile	07825244520		
Fax			

a) Approximately how much time will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalents (WTE).*
0.2

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? (●) Yes ( ) No

A copy of a current CV for the Principal Investigator (maximum 2 pages of A4) must be submitted with this form.

3. Please give details of all locations, departments, groups or units at which or through which research procedures will be conducted at this site and describe the activity that will take place.

Please list all locations/departments etc where research procedures will be conducted within the NHS organisation, describing the involvement in a few words. Where access to specific facilities will be required these should also be listed for each location.

Name the main location/department first. Give details of any research procedures to be carried out off site, for example in participants' homes.

	Location	Activity/facilities
1	Bangor Child and Adolescent Mental Health Service	Initial consent to be contacted by the research officer will be sought by assigned DBT Clinician. Research team members will request access to a quiet clinic room to conduct meetings with parents/carers and young people, semi-structured interview and questionnaire completion. Team family therapist will require access to a quiet clinic room to conduct Family Domains Therapy. Where participants prefer meeting research assistant in their own home for data collection this will be considered.
2	Conwy Child and Adolescent Mental Health Service	Initial consent to be contacted by the research officer will be sought by assigned DBT Clinician. Research team members will request access to a quiet clinic room to conduct meetings with parents/carers and young people, semi-structured interview and questionnaire completion. Team family therapist will require access to a quiet clinic room to conduct Family Domains Therapy. Where participants prefer meeting research assistant in their own home for data collection this will be considered.
3	Denbighshire Child and	Initial consent to be contacted by the research officer will be sought by assigned DBT Clinician. Research team members will request access to a quiet clinic room to conduct meetings with

	Adolescent Mental Health Service	parents/carers and young people, semi-structured interview and questionnaire completion. Team family therapist will require access to a quiet clinic room to conduct Family Domains Therapy. Where participants prefer meeting research assistant in their own home for data collection this will be considered.
4	Wrexham Child and Adolescent Mental Health Service	Initial consent to be contacted by the research officer will be sought by assigned DBT Clinician. Research team members will request access to a quiet clinic room to conduct meetings with parents/carers and young people, semi-structured interview and questionnaire completion. Team family therapist will require access to a quiet clinic room to conduct Family Domains Therapy. Where participants prefer meeting research assistant in their own home for data collection this will be considered.
5	Flintshire Child and Adolescent Mental Health Service	Initial consent to be contacted by the research officer will be sought by assigned DBT Clinician. Research team members will request access to a quiet clinic room to conduct meetings with parents/carers and young people, semi-structured interview and questionnaire completion. Team family therapist will require access to a quiet clinic room to conduct Family Domains Therapy. Where participants prefer meeting research assistant in their own home for data collection this will be considered.

5. Please give details of all other members of the research team at this site.

1

Title	Forename/Initials	Surname
	To be employed	

Work E-mail	
Employing organisation	Betsi Cadwaladr University Health Board
Post	Research Assistant Psychologist - Band 4
Qualifications	Psychology Degree
Role in research team:	researcher

a) Approximately how much time (approximately) will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalents (WTE).*
1.0

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? ○ Yes ◉ No

A copy of a current CV for the research team member (maximum 2 pages of A4) must be submitted to the R&D office.

2

Title	Forename/Initials	Surname
Ms	Garvey	Victoria

Work E-mail	Victoria.Garvey@wales.nhs.uk
Employing organisation	BCUHB
Post	Honorary Assistant Psychologist
Qualifications	PgCert Public Health BSc Applied Psychology (Hons) - 1st Additional research training: Communicating with research participants Good Clinical Practice
Role in research team:	researcher

a) Approximately how much time (approximately) will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalents (WTE).*
0.2

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? ◉ Yes ○ No

A copy of a current CV for the research team member (maximum 2 pages of A4) must be submitted to the R&D office.

3

	Title	Forename/Initials	Surname
	Miss	Stefania	(Parks) Pethica
Work E-mail	psp4fd@bangor.ac.uk		
Employing organisation	BCUHB		
Post	Trainee Clinical Psychologist		
Qualifications	Currently on NWCPP DPsyClin programme PgDip Applied Systemic Theory Bsc Personality Psychology and Interpersonal Relationships		
Role in research team:	researcher		

a) Approximately how much time (approximately) will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalents (WTE).*
0.64 between September 2016 and March 2017 as part of research work for doctoral thesis

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? ◉ Yes ○ No

A copy of a current CV for the research team member (maximum 2 pages of A4) must be submitted to the R&D office.

6. Does the Principal Investigator or any other member of the site research team have any direct personal involvement (e.g. financial, share-holding, personal relationship etc) in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

7. What is the proposed local start and end date for the research at this site?

Start date:	01/01/2016
End date:	31/03/2017
Duration (Months):	14

8-1. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *(These include seeking consent, interviews, non-clinical observations and use of questionnaires.)*

Columns 1-4 have been completed with information from A18 as below:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.

2. If this intervention would have been routinely given to participants as part of their care, how many of the total would have been routine?

3. Average time taken per intervention (minutes, hours or days)

4. Details of who will conduct the procedure, and where it will take place

Please complete Column 5 with details of the names of individuals or names of staff groups who will conduct the procedure at this site.

Intervention or procedure	1	2	3	4	5
Preliminary explanation and information stage - parents/carers and young people.	1	1	5 min	DBT lead when discussing DBT intervention with young person and parents/carers. To take place in a quiet room at local CAMHS.	Assigned DBT clinician
Detailed information about the study and domains based family therapy. Parents/carers and young people.	1	n/a	30 min	Research Officer. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers. Parents/carers and young person to be seen separately if wished by young person.	Research Officer Victoria Garvey
General Health Questionnaire. Parents/carers only.	2	n/a	5 min	Research Assistant. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers.Delivered pre-post young person's DBT intervention.	Research Assistant Psychologist - band 4 (to be employed)
5 minute speech sample describing young person - parents/carers only	2	n/a	5 min	Research Assistant. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers. One speech sample collected at beginning of research one collected after young person has completed DBT intervention.	Research Assistant Psychologist - band 4 (to be employed)
Beck Depression Inventory - II. Parents/carers only	2	n/a	5 min	Research Assistant. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers. Delivered pre-post young person's DBT intervention.	Research Assistant Psychologist - band 4 (to be employed)
DBT Ways of coping checklist - young person only	2	2	5 min	Research assistant. To take place in a quiet room at local CAMHS.	Research Assistant Psychologist - band 4 (to be employed)
Lifetime parasuicide count, semi-structured interview - young person only	2	2	30 min	Research assistant. To take place in a quiet room at local CAMHS. (During this appointment the measures below will also be taken: Borderline symptom checklist-23, Zanarini rating scale)	Research Assistant Psychologist - band 4 (to be employed)
Borderline symptom list 23 - young person only	2	2	5 min	Research assistant. To take place in a quiet room at local CAMHS.	Research Assistant Psychologist - band 4 (to be employed)
Zanarini rating scale for borderline personality disorder - young person only	2	n/a	30 min	Research assistant. To take place in a quiet room at local CAMHS.	Research Assistant Psychologist - band 4 (to be employed)
Feedback to young people and parents/carers	1	n/a	5 min	Information about outcome and request of young person's and	Research Assistant Psychologist - band 4 (to be

			parent/carers's opinion of findings sent by post with enclosed return envelope included.	employed)
Parent Child Emotions and Behaviours Questionniare - Parents/carers only	2	n/a	5 min	Research Assistant. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers. Delivered pre-post young person's DBT intervention.	Research Assistant Psychologist - band 4 (to be employed)
Parent Orientation Questionnaire - parents/carers only	2	n/a	5 min	Research Assistant. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers.Delivered pre-post young person's DBT intervention.	Research Assistant Psychologist - band 4 (to be employed)
SCORE-15 - parents/carers only	1	n/a	5min	Research Assistant. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers.Delivered pre-post young person's DBT intervention.	Research Assistant Psychologist - band 4 (to be employed)
Means End Problem Solving Task - young person and parent/carers	2	n/a	30 min	Research assistant. To take place in a quiet room at local CAMHS.	Research Assistant Psychologist - band 4 (to be employed)
Interview on the decision to opt in or out of FDT and its benefits	1	n/a	45min	Research Assistant or Trainee Clinical Psychologist. To take place in a quiet room at local CAMHS or at family home as preferred by parents/carers.Delivered pre-post young person's DBT intervention.	Research Assistant Psychologist - band 4 (to be employed) or Trainee Clinical Psychologist (Stefania Pethica)
Helpful Aspects of Therapy Form	1	n/a	5min	This form is a session-by-session rating form will be collected at the end of each FDT therapy session. It will be collected by the family therapist delivering the intervention. Parents/Carers will complete as many as number of sessions they undergo.	Assigned Family Therapist

8-2. Will any aspects of the research at this site be conducted in a different way to that described in Part A or the protocol?

○ Yes ◉ No

If Yes, please note any relevant changes to the information in the above table.

Are there any changes other than those noted in the table?

9-1. Give details of any clinical intervention(s) or procedure(s) to be received by participants as part of the research protocol. *(These include uses of medicinal products or devices, other medical treatments or assessments, mental health interventions, imaging investigations and taking samples of human biological material. Include procedures which might be received as routine clinical care outside of the research.)*

Columns 1-4 have been completed with information from A19 as below:

1. *Total number of interventions to be received by each participant as part of the research protocol*
2. *If this intervention would have been routinely given to participants as part of their care, how many of the total would have been routine?*
3. *Average time taken per intervention (minutes, hours or days)*
4. *Details of who will conduct the procedure, and where it will take place*

Please complete Column 5 with details of the names of individuals or names of staff groups who will conduct the procedure at this site.

Intervention or procedure	1	2	3	4	5
Standard DBT intervention for young people with emerging borderline personality disorder - individual therapy	20	20	1 hour	Assigned local CAMHS clinician. Intervention will take place at local CAMHS.	Local DBT team.
Standard DBT intervention for young people with emerging borderline personality disorder - skills training group	22	22	2 hours	Assigned local CAMHS clinician. Intervention will take place at local CAMHS.	Local DBT team.
Family Domains Therapy intervention for parents/carers	10	n/a	1 hour	Local CAMHS Family therapist. Intervention will take place at local CAMHS. Total number of interventions will depend on family functioning, an estimate of eight sessions per family will be provided. However should families need more sessions they will be provided in accordance with the family's needs.	BCUHB emplyed family therapists. Steve Riley, Paul Tranter and Heather Lee.

9-2. Will any aspects of the research at this site be conducted in a different way to that described in Part A or the protocol?

○ Yes ◉ No

If Yes, please note any relevant changes to the information in the above table.

Are there any changes other than those noted in the table?

10. How many research participants/samples is it expected will be recruited/obtained from this site?

Approximately 20, this number is based on currentl levels of referrals to CAMHS for DBT interventions and an estimation of how many referred individuals will accept to take part in the study.

11. Give details of how potential participants will be identified locally and who will be making the first approach to them to take part in the study.

Participants will be identified by local CAMHS care teams. This process will take place during the course of their normal screening of referrals for DBT. Assigned DBT clinician will first approach young people and their parents/carers during their first meeting and inform them of the research and seek consent to be contacted by the research assistant.

12. Who will be responsible for obtaining informed consent at this site? What expertise and training do these persons have in obtaining consent for research purposes?

Name	Expertise/training
Victoria Gravey	Communicating with Research Participants training - November 2014 Good Clinical Practice Training - July 2014

15-1. Is there an independent contact point where potential participants can seek general advice about taking part in research?

Parents/Carers and Young people will be given the contact details of their local Research Ethics Committee Chair to contact for general advice about taking part in research and whether they have concerns regarding the research project.

15-2. Is there a contact point where potential participants can seek further details about this specific research project?

Yes. The research officer's and Dr Michaela Swales's contact details will be made available in the Participant Information Sheet.

16. Are there any changes that should be made to the generic content of the information sheet to reflect site-specific issues in the conduct of the study? *A substantial amendment may need to be discussed with the Chief Investigator and submitted to the main REC.*

No.

Please provide a copy on headed paper of the participant information sheet and consent form that will be used locally. Unless indicated above, this must be the same generic version submitted to/approved by the main REC for the study while including relevant local information about the site, investigator and contact points for participants (see guidance notes).

17. What local arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters etc.)*

The nature of the tasks included in the study requires a good level of English comprehension, and therefore individuals who do not fulfil this criteria will not be recruited for the study. This is to both preserve the integrity of the data produced and to prevent wasting time and/or causing undue stress or embarrassment to individuals without the required level of English comprehension for the tasks at hand.

18. What local arrangements will be made to inform the GP or other health care professionals responsible for the care of the participants?

The young person's care coordinator and the assigned DBT clinician inside the CAMHS team will be informed of the young person's decision to take part in the research. Following the receipt of consent from the parents/carers and young person a letter will be sent to the family's GP to inform of the participation in the research project together with a copy of the parent/carer and young person information sheets.

19. What arrangements (e.g. facilities, staffing, psychosocial support, emergency procedures) will be in place at the site, where appropriate, to minimise the risks to participants and staff and deal with the consequences of any harm?

DBT therapists and family therapists will have weekly meetings to discuss outcomes and risk management. The

participants will receive in their participant information sheet the contact details of local REC committee chairs and Dr Michaela Swales. The research officer, research assistant and trainee clinical psychologist will receive supervision by Dr Michaela Swales.

20. What are the arrangements for the supervision of the conduct of the research at this site? *Please give the name and contact details of any supervisor not already listed in the application.*

The research officer, research assistant and trainee clinical psychologist will receive supervision by Dr Michaela Swales. Trainee Clinical Psychologist will also receive research supervision by Dr Mike Jackson.
DBT therapists and family therapists will also have weekly meetings to discuss outcomes and risk management.

21. What external funding will be provided for the research at this site?

○ Funded by commercial sponsor
◉ Other funding
○ No external funding

Please give details of the funding:
Funding from BCUHB Pathway to Portfolio (P2P) funding stream.

Type of funding	Details (including breakdown over years if appropriate)
(i) Block grant	£38456
(ii) Per participant	
(iii) Other (give details)	

Which organisation will receive and manage this funding?
BCUHB

23. Authorisations required prior to R&D approval

The local research team are responsible for contacting the local NHS R&D office about the research project. Where the research project is proposed to be coordinated centrally and therefore there is no local research team, it is the responsibility of the central research team to instigate this contact with local R&D.

NHS R&D offices can offer advice and support on the set-up of a research project at their organisation, including information on local arrangements for support services relevant to the project. These support services may include clinical supervisors, line managers, service managers, support department managers, pharmacy, data protection officers or finance managers depending on the nature of the research.

Obtaining the necessary support service authorisations is not a pre-requisite to submission of an application for NHS research permission, but all appropriate authorisations must be in place before NHS research permission will be granted. Processes for obtaining authorisations will be subject to local arrangements, but the minimum expectation is that the local R&D office has been contacted to notify it of the proposed research project and to discuss the project's needs **prior** to submission of the application for NHS research permission via IRAS.

Failure to engage with local NHS R&D offices **prior** to submission may lead to unnecessary delays in the process of this application for NHS research permissions.

Declaration:
☑ **I confirm that the relevant NHS organisation R&D office has been contacted to discuss the needs of the project and local arrangements for support services. I understand that failure to engage with the local NHS R&D office before submission of this application may result in unnecessary delays in obtaining NHS research permission for this project.**

Please give the name and contact details for the NHS R&D office staff member you have discussed this application

with:

Please note that for some sites the NHS R&D office contact may not be physically based at the site. For contact details refer to the guidance for this question.

	Title	Forename/Initials	Surname
	Dr	Rossela	Roberts
Work E-mail	rossela.roberts@bangor.ac.uk		
Work Telephone			

Declaration by Principal Investigator or Local Collaborator

1. The information in this form is accurate to the best of my knowledge and I take full responsibility for it.
2. I undertake to abide by the ethical principles underpinning the World Medical Association's Declaration of Helsinki and relevant good practice guidelines in the conduct of research.
3. If the research is approved by the main REC and NHS organisation, I undertake to adhere to the study protocol, the terms of the application of which the main REC has given a favourable opinion and the conditions requested by the NHS organisation, and to inform the NHS organisation within local timelines of any subsequent amendments to the protocol.
4. If the research is approved, I undertake to abide by the principles of the Research Governance Framework for Health and Social Care.
5. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to the conduct of research.
6. I undertake to disclose any conflicts of interest that may arise during the course of this research, and take responsibility for ensuring that all staff involved in the research are aware of their responsibilities to disclose conflicts of interest.
7. I understand and agree that study files, documents, research records and data may be subject to inspection by the NHS organisation, the sponsor or an independent body for monitoring, audit and inspection purposes.
8. I take responsibility for ensuring that staff involved in the research at this site hold appropriate contracts for the duration of the research, are familiar with the Research Governance Framework, the NHS organisation's Data Protection Policy and all other relevant policies and guidelines, and are appropriately trained and experienced.
9. I undertake to complete any progress and/or final reports as requested by the NHS organisation and understand that continuation of permission to conduct research within the NHS organisation is dependent on satisfactory completion of such reports.
10. I undertake to maintain a project file for this research in accordance with the NHS organisation's policy.
11. I take responsibility for ensuring that all serious adverse events are handled within the NHS organisation's policy for reporting and handling of adverse events.
12. I understand that information relating to this research, including the contact details on this application, will be held by the R&D office and may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
13. I understand that the information contained in this application, any supporting documentation and all correspondence with the R&D office and/or the REC system relating to the application will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.

This section was signed electronically by Dr Michaela Swales on 04/01/2016 19:38.

Job Title/Post: Consultant Psychologist

Organisation: BCUHB

Email: m.swales@bangor.ac.uk

ETHICS APPENDIX X

R&D Approval Letter

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol
Betsi Cadwaladr
University Health Board

Panel Arolygu Mewnol Y&D - Canolog
R&D Internal Review Panel

Betsi Cadwaladr University Health Board
Ysbyty Gwynedd
Clinical Academic Office
Bangor, Gwynedd
LL57 2PW

Chairman/Cadeirydd – Dr Nefyn Williams PhD, FRCGP
Email: rossela.roberts@wales.nhs.uk
debra.slater@wales.nhs.uk
sion.lewis@wales.nhs.uk
Tel/Fax: 01248 384 877

Dr Michaela Swales
Consultant Clinical Psychologist & Senior Lecturer
BCUHB North Wales Clinical Psychology Programme
Bangor University
Bangor,
Gwynedd
LL57 2DG m.swales@bangor.ac.uk

25th February 2016

Dear Dr Swales

Re: Confirmation that R&D governance checks are complete / R&D approval granted

Study Title	A feasibility study investigating the provision of a Family Domains Therapy (FDT) intervention for the parents/carers of self-harming young people undergoing Dialectical Behaviour Therapy (DBT) in North Wales
IRAS reference	186533
REC reference	16/WA/0025

The above research project was reviewed at the meeting of the BCUHB R&D Internal Review Panel

The Panel is satisfied with the scientific validity of the project, the risk assessment, the review of the NHS cost and resource implications and all other research management issues pertaining to the application.

The Internal Review Panel is pleased to confirm that all governance checks are now complete and to grant approval to proceed at Betsi Cadwaladr University Health Board sites as described in the application.

The documents reviewed and approved are listed below:

Document:	Version:	Date:
R&D Form	V5.2.0	04/01/2016
SSI Form	V5.2.0	04/01/2016
Protocol	V1	04/11/2015
Information sheet (Young person)	V2	16/12/2014
Information sheet (Parents/Carers)	V2	16/12/2014
Information FDT (Parent/Carers)	V2	16/12/2014
Consent Form to contact (Parents/Carers)	V2	16/12/2014
Consent Form to contact (Young person)	V2	16/12/2015
Consent Form (Parents/Carers)	V2	16/12/2015
Consent Form (Guardian)	V2	16/12/2015
Assent Form (Young person)	V2	16/12/2015
GP Letter	V1	04/11/2015
Questionnaire - Helpful Aspects of Therapy Scale	V2	16/12/2015
Questionnaire – Parent/Child Emotions & Behaviours	V1	04/11/2015
Questionnaire – Parent Orientation	V1	04/11/2015
Means Ends Problems Test - Instructions	V1	04/11/2015
Summary CV: Swales		Feb 2015
Summary CV: Jackson		2015
Summary CV: Pethica		2015

Document:	Version:	Date:
Summary CV:Jones		22/02/2016
Evidence of Insurance (UMAL)		Expires 31/07/2016
Evidence of funding P2P letter/application		22/01/2015
Risk Assessment		22/01/2016
REC Favourable opinion Letter		22/01/2016

All research conducted at the Betsi Cadwaladr University Health Board sites must comply with the Research Governance Framework for Health and Social Care in Wales (2009). An electronic link to this document is provided on the BCUHB R&D WebPages. Alternatively, you may obtain a paper copy of this document via the R&D Office.

Attached you will find a set of approval conditions outlining your responsibilities during the course of this research. Failure to comply with the approval conditions will result in the withdrawal of the approval to conduct this research in the Betsi Cadwaladr University Health Board.

If your study is adopted onto the NISCHR Clinical Research Portfolio (CRP), it will be a condition of this NHS research permission, that the Chief Investigator will be required to regularly upload recruitment data onto the portfolio database. To apply for adoption onto the NISCHR CRP, please go to: http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=31979. Once adopted, NISCHR CRP studies may be eligible for additional support through the NISCHR Clinical Research Centre. Further information can be found at:http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=28571 and/or from your NHS R&D office colleagues.

To upload recruitment data, please follow this link:
http://www.crncc.nihr.ac.uk/about_us/processes/portfolio/p_recruitment.
Uploading recruitment data will enable NISCHR to monitor research activity within NHS organizations, leading to NHS R&D allocations which are activity driven. Uploading of recruitment data will be monitored by your colleagues in the R&D office. If you need any support in uploading this data, please contact debra.slater@wales.nhs.uk or sion.lewis@wales.nhs.uk

If you would like further information on any other points covered by this letter please do not hesitate to contact me.

On behalf of the Panel, may I take this opportunity to wish you every success with your research.

Yours sincerely,

Dr Nefyn Williams PhD, FRCGP
Director of R&D
Chairman Internal Review Panel

Copy to:

Sponsor:
Hefin Francis
School of Psychology Adeilad Brigantia
Penrallt Road Gwynedd
Bangor
LL57 2AS

Student:
Mrs Stefania Pethica
50 Kensington Avenue
Old Colwyn
Colwyn Bay
LL29 9ST psp4fd@bangor.ac.uk

Academic Supervisors:
Dr Mike Jackson
North Wales Clinical Psychology Programme
Bangor University
Bangor,
LL57 2DG

ETHICS APPENDIX XI

Young Person Assent and Parent/Carer Consent to be Contacted by Researcher Forms

COLEG IECHYD A GWYDDORAU YMDDYGIAD
COLLEGE OF HEALTH & BEHAVIOURAL SCIENCES

YSGOL SEICOLEG
SCHOOL OF PSYCHOLOGY

RHAGLEN SEICOLEG CLINIGOL GOGLEDD CYMRU
NORTH WALES CLINICAL PSYCHOLOGY PROGRAMME

PRIFYSGOL BANGOR UNIVERSITY

CONSENT TO CONTACT FOR RESEARCH PURPOSES

Hi,

Your local CAMHS is participating in a research project on how to support the young people like you who have been referred for DBT and their parents/carers.

You are being invited to give consent for our researcher, Victoria Garvey, to contact you at some time in the following week to invite you to participate in this research study.

What is this form?

This is NOT a consent to participate in the research study. It is only a consent to use your contact details so Victoria can contact you about our research study.

What happens if I consent?

If you consent you will receive an information sheet about our research. It will explain the reason why we are doing this research and what it would mean for you to participate in it. You will also be contacted by our researcher, Victoria. She will meet up with you to talk about the study and see if you want to participate in it.

What happens after I meet with the researcher?

After you meet Victoria, you can tell her if you want to participate in the study or not. You don't have to. It is up to you.

What happens if I don't consent?

If you don't consent nothing will happen. Your relationship with your therapist and your treatment will not be affected.

If you have any questions or comments, please Victoria Garvey, Research Officer, on 01248 383615 or call the Research Lead, Dr Michaela Swales, on 01248 382552.
Thank you for your attention.

If you want to give consent for Victoria to contact you about this research, please sign:

Name: _____ Signature: _____

COLEG IECHYD A GWYDDORAU YMDDYGIAD
COLLEGE OF HEALTH & BEHAVIOURAL SCIENCES

YSGOL SEICOLEG
SCHOOL OF PSYCHOLOGY

PRIFYSGOL BANGOR UNIVERSITY

RHAGLEN SEICOLEG GLINIGOL GOGLEDD CYMRU
NORTH WALES CLINICAL PSYCHOLOGY PROGRAMME

CANIATÂD I GYSYLLTU AT DDIBENION YMCHWIL

Helo,

Mae eich Gwasanaethau Iechyd Meddwl Plant a'r Glasoed (CAMHS) lleol yn cymryd rhan mewn project ymchwil ar sut i gefnogi pobl ifanc fel chi sydd wedi eu cyfeirio at Therapi Ymddygiad Dialectig (DBT) a'u rhieni/gofalwyr.

Fe'ch gwahoddir i roi caniatâd i'n hymchwilydd, Victoria Garvey, gysylltu â chi rywbryd yn ystod yr wythnos nesaf i'ch gwahodd i gymryd rhan yn yr astudiaeth ymchwil hon.

Beth yw'r ffurflen hon?

NID ffurflen gydsynio i gymryd rhan yn yr astudiaeth ymchwil yw'r ffurflen hon. Dim ond ffurflen ganiatâd i ddefnyddio'ch manylion cysylltu er mwyn i Victoria allu cysylltu â chi ynglŷn â'n hastudiaeth ymchwil ydyw.

Beth fydd yn digwydd os ydw i'n cydsynio?

Os byddwch yn cydsynio byddwch yn cael taflen wybodaeth am ein hymchwil. Bydd yn egluro'r rheswm pam rydym yn gwneud yr ymchwil a beth fyddai cymryd rhan ynddo yn ei olygu i chi. Bydd ein hymchwilydd, Victoria, yn cysylltu gyda chi hefyd. Bydd hi'n eich cyfarfod i siarad am yr astudiaeth er mwyn gweld a ydych eisiau cymryd rhan.

Beth sy'n digwydd ar ôl i mi gwrdd â'r ymchwilydd?

Ar ôl ichi gwrdd â Victoria gallwch ddweud wrthi a ydych eisiau cymryd rhan yn yr astudiaeth neu beidio. Nid oes raid i chi. Chi sydd i benderfynu hynny.

Beth sy'n digwydd os nad ydw i'n cydsynio?

Os na fyddwch yn cydsynio, ni fydd dim byd yn digwydd. Ni fydd eich perthynas gyda'ch therapydd na'ch triniaeth yn cael eu heffeithio.

Os oes gennych unrhyw gwestiynau neu sylwadau, cysylltwch â Victoria Garvey, Swyddog Ymchwil, ar 01248 383615 neu ffoniwch Arweinydd yr Ymchwil, Dr Michaela Swales, ar 01248 382552. Diolch i chi am eich sylw.

Os hoffech roi caniatâd i Victoria gysylltu â chi, arwyddwch isod:

Enw: _____ Llofnod: _____

COLEG IECHYD A GWYDDORAU YMDDYGIAD
COLLEGE OF HEALTH & BEHAVIOURAL SCIENCES

YSGOL SEICOLEG
SCHOOL OF PSYCHOLOGY

PRIFYSGOL BANGOR UNIVERSITY

RHAGLEN SEICOLEG CLINIGOL GOGLEDD CYMRU
NORTH WALES CLINICAL PSYCHOLOGY PROGRAMME

CONSENT TO CONTACT FOR RESEARCH PURPOSES

Dear Parent/Carer,

Your local CAMHS is participating in a research project on how to evaluate Dialectical Behaviour Therapy (DBT) and how best to support parents/carers of young people who are receiving DBT. You and your young person are being invited to give consent for a researcher, Victoria Garvey, to contact you at some time in the following week to invite you to participate in this research study.

What is this form?

This is NOT a consent to participate in the research study. It is only a consent to use your contact information in order to contact you and your young person about our research study.

What happens if I consent?

If you consent you and your young person will receive an information sheet about the aims and purposes of our research. You and your young person will also be contacted by Victoria Garvey, researcher, in the following week. Victoria will meet with you and your young person to inform you about our research study and what it would mean for you and for your young person to participate.

What happens after I meet with the researcher?

After you meet with Victoria you and your young person can choose if you want to participate in our research study or not. Victoria will ask for your consent to participate in our research study and your consent to allow your young person to participate in the study.

What happens if I don't consent?

If you don't consent nothing will happen. Your young person's treatment will not be affected in any way.

If you have any questions or comments, please contact Victoria Garvey, Research Officer, on 01248 383615 or call the Research Lead, Dr Michaela Swales, on 01248 382552.

Thank you for your attention.

If you want to give consent for you and your young person to be contacted by our researcher, Victoria Garvey, please sign below:

Name: _____ Signature: _____

COLEG IECHYD A GWYDDORAU YMDDYGIAD
COLLEGE OF HEALTH & BEHAVIOURAL SCIENCES

YSGOL SEICOLEG
SCHOOL OF PSYCHOLOGY

PRIFYSGOL BANGOR UNIVERSITY

RHAGLEN SEICOLEG GLINIGOL GOGLEDD CYMRU
NORTH WALES CLINICAL PSYCHOLOGY PROGRAMME

CANIATÂD I GYSYLLTU AT DDIBENION YMCHWIL

Annwyl Riant/Gofalwr,

Mae eich Gwasanaethau Iechyd Meddwl Plant a'r Glasoed (CAMHS) lleol yn cymryd rhan mewn project ymchwil ar sut i werthuso Therapi Ymddygiad Dialectig (DBT) a beth yw'r ffordd orau o gefnogi rhieni/gofalwyr pobl ifanc sy'n derbyn DBT. Fe'ch gwahoddir chi a'ch person ifanc i roi caniatâd i ymchwilydd, Victoria Garvey, gysylltu â chi rywbryd yn ystod yr wythnos nesaf i'ch gwahodd i gymryd rhan yn yr astudiaeth ymchwil hon.

Beth yw'r ffurflen hon?

NID ffurflen ganiatâd i gymryd rhan yn yr astudiaeth ymchwil yw'r ffurflen hon. Dim ond ffurflen ganiatâd i ddefnyddio'ch manylion cysylltu er mwyn cysylltu â chi a'ch person ifanc ynglŷn â'n hastudiaeth ymchwil ydyw.

Beth fydd yn digwydd os ydw i'n cydsynio?

Os byddwch yn cydsynio byddwch chi a'ch person ifanc yn cael taflen wybodaeth am amcanion a dibenion ein hymchwil. Bydd Victoria Garvey, ymchwilydd, yn cysylltu â chi a'ch person ifanc yn ystod yr wythnos ganlynol. Bydd Victoria'n cwrdd â chi a'ch person ifanc er mwyn rhoi gwybod ichi am ein hastudiaeth ymchwil a beth fyddai cymryd rhan yn ei olygu i chi a'ch person ifanc.

Beth sy'n digwydd ar ôl i mi gwrdd â'r ymchwilydd?

Ar ôl ichi gwrdd â Victoria cewch chi a'ch person ifanc ddewis a ydych am gymryd rhan yn ein hastudiaeth achos neu beidio. Bydd Victoria'n gofyn am eich cydsyniad i gymryd rhan yn ein hastudiaeth ymchwil a'ch caniatâd i adael i'ch person ifanc gymryd rhan yn yr astudiaeth.

Beth sy'n digwydd os nad ydw i'n cydsynio?

Os na fyddwch yn cydsynio, ni fydd dim byd yn digwydd. Ni fydd triniaeth eich person ifanc yn cael ei heffeithio mewn unrhyw ffordd. Os oes gennych unrhyw gwestiynau neu sylwadau, cysylltwch â Victoria Garvey, Swyddog Ymchwil, ar 01248 383615 neu ffoniwch Arweinydd yr Ymchwil, Dr Michaela Swales, ar 01248 382552.

Diolch i chi am eich sylw.

Os hoffech roi caniatâd i'n hymchwilydd, Victoria Garvey, gysylltu â chi a'ch person ifanc, arwyddwch isod:

Enw: _____ Llofnod: _____

ETHICS APPENDIX XII

Information Sheet for Young People

COLEG IECHYD A GWYDDORAU YMDDYGIAD
COLLEGE OF HEALTH & BEHAVIOURAL SCIENCES

YSGOL SEICOLEG
SCHOOL OF PSYCHOLOGY

RHAGLEN SEICOLEG CLINIGOL GOGLEDD CYMRU
NORTH WALES CLINICAL PSYCHOLOGY PROGRAMME

PRIFYSGOL BANGOR UNIVERSITY

INFORMATION SHEET FOR YOUNG PERSON

REC Reference Number: 16/WA/0025

A study on how best to support young people going through DBT and their Parents/Carers.

Why have I been invited to take part?

We are inviting all young people who have been referred for DBT in North Wales and their parents/carers to take part in this research. We have sent you this information via your DBT therapist so your personal information is completely confidential and you are free to decide if you want to take part, or no. If you decide "No" then that isn't a problem. However, we do hope you can help

Information about the research

We are from Bangor University and Betsi Cadwaladr University Health Board (BCUHB) and we are asking you to be in our research study. You should only participate if you want to. Before you decide if you want to take part, it is important for you to understand why we are doing this research and what it will mean for you if you take part.

Please take time to read the information on this sheet carefully and discuss it with others if you want to. The Research Officer, Victoria Garvey, will be in touch with you after you have received this sheet and you can ask her if there is anything that is not clear or if you would like more information.

Research team

Dr Michaela Swales, Clinical Psychologist (BCUHB)
Prof Jonathan Hill, Professor of Child and Adolescent Psychiatry (University of Reading)
Dr Mike Jackson, Clinical Psychologist (BCUHB)
Stefania Pethica, Trainee Clinical Psychologist (BCUHB, Bangor University)
Victoria Garvey, Research Officer (BCUHB)
Katy Jones, Research Assistant (BCUHB)

What is this study about?

This study is finding out the best ways to assess outcomes for Dialectical Behaviour Therapy (DBT), and finding out how to support the parents/carers of young people like you who have been referred to DBT.

We will find out about the best way to assess if DBT works by asking you to fill in two questionnaires, take part in two interviews and do a problem-solving task before you begin DBT and at the end of your therapy.

Your parent/carer will also be asked to take part in interviews if they consent to take part in this study. They will also be offered Family Domains Therapy (FDT), a new intervention for parents/carers of young people referred to DBT.

Do I have to take part?

Participation is voluntary. You do not have to take part. It is up to you. You should read this information sheet and if you have any questions you should ask Victoria, Research Officer, when she comes to meet you. You can say no now, or you can even change your mind later. You don't have to give a reason for dropping out. No one will be upset with you if you decide not to be in this study.

What are you asking me to do?

If you decide to take part we will ask you to sign a consent form. Victoria will then discuss the research procedure with you.

1. Firstly, you will arrange to meet with our Research Assistant in a private place (for confidentiality reasons) at your local CAMHS. During this meeting the Research Assistant will give you 2 questionnaires to fill in. The Research Assistant will then interview you about the problems that you have been having that led to your referral to DBT. This meeting will be approximately 1 hour and a half long, however, you can always stop if you find it too long and continue it in another meeting.

2. Secondly, you will be asked to do a problem-solving assessment. DBT tries to help young people by improving their problem-solving skills, that's why we are asking you to do this, to see if DBT helps you with this as well. We will ask you to bring along your parent/carer for this assessment, so that they are there to help you if you would like their help. This assessment will be video recorded.

3. Finally, after you have finished DBT, the Research Assistant will get back in touch with you and you will be asked to do all of these things all over again. This is so we can really see how much DBT works.

All interviews will be recorded. All recordings of data on audio-equipment is deleted we have transcribed the interviews. Even if you have decided to take part, you are still free to stop participating at any time during the meetings with the Research Assistant.

What if I do not want to take part?

Participation is voluntary. Deciding not to take part will not impact any aspect of your treatment or your relationship with your therapist.

Who is going to know that I am taking part in this research?

Only your CAMHS clinicians and your GP will know that you are taking part in this research. We will tell your GP by sending them a letter. We tell GPs about research projects so they know what treatment you are receiving.

Welsh Language

Information about the study will be provided bilingually. Unfortunately, all research interviews will be done in English. We are doing this to maintain a consistency in the data we collect, which is important for our research. However, you can access DBT in Welsh if you want to, just speak with your DBT therapist.

What are the possible benefits and risks of taking part?

The information we get from the study will help us to know how to decide on the best way to measure how well DBT works and also how to support young people like you and their parents/carers. By taking part in this research you will help with the development of services for young people and their parents/carers. In addition, we will provide you with a summary of a final report describing what we have found out from this research.

The main risk to taking part in this study is that answering questionnaires and taking part in interviews can bring up uncomfortable emotions. However, many young people find that these conversations can be good as well because during the interviews you can tell your point of view on the difficulties experienced at home or at school. All members of the research team are trained in conducting such interviews and you can stop the interview at any point without giving a reason if you find it too uncomfortable.

If I do take part, will it be confidential?

What you say in the interviews and the questionnaires you fill in is strictly confidential and will be held securely until the research is finished. All data for analysis will be anonymised. This means that we will never reveal the names of any participants. At all times there will be no possibility of you as individual being linked with the data.

However, if you say to one of the researchers that you or someone else is at risk of serious harm the researcher will have to contact your DBT therapist and let them know that they think you or someone else is at risk.

The UK Data Protection Act 1998 will apply to all information you give us in the interviews. The information will be held on password-locked computer files and locked cabinets within BCUHB. No data will be accessed by anyone other than the research team; and anonymity of the material will be protected by using false names. No data will be able to be linked back to any individual taking part in this study.

How is the project being funded?

The project is being funded by Betsi Cadwaladr University Health Board.

What will happen to the results of the study?

We will write a report summarising the main results of our study, which will be sent to you. We also plan to disseminate the research findings through publications and conferences.

Who should I contact for further information?

If you have any questions or if you want more information about this study, please contact Victoria Garvey or Dr Michaela Swales using the following contact details:

Victoria Garvey Research Officer Betsi Cadwaladr University Health Board School of Medical Sciences Bangor University BANGOR LL57 2AS Tel: +44 (0)1248 383615 Email: Victoria.Garvey@wales.nhs.uk	Dr Michaela Swales North Wales Clinical Psychology Programme / Rhaglen Seicoleg Clinigol Gogledd Cymru, School of Psychology / Ysgol Seicoleg Bangor University / Prifysgol Bangor BANGOR LL57 2DG Tel: +44 (0)1248 382552 Email: m.swales@bangor.ac.uk

What if something goes wrong?

If this study has harmed you or your young person in any way or if you wish to make a complaint about the conduct of the study you can mention it to your DBT therapist or you can contact these people, using the details below for further advice and information.

School of Psychology – Head of School Prof John Parkinson Adeilad Brigantia Penrallt Road Gwynedd LL57 2AS United Kingdom Tel: +44 (0)1248 38 2211 Fax: +44 (0)1248 38 2599 Email: j.parkinson@bangor.ac.uk	School of Psychology - School Manager Mr Hefin Francis Adeilad Brigantia Penrallt Road Gwynedd LL57 2AS United Kingdom Tel: +44 (0) 1248 388339 Fax: +44 (0) 1248 38 2599 Email: h.francis@bangor.ac.uk

Thank you for reading this information sheet and thinking about taking part in this research.

COLEG IECHYD A GWYDDORAU YMDDYGIAD
COLLEGE OF HEALTH & BEHAVIOURAL SCIENCES

YSGOL SEICOLEG
SCHOOL OF PSYCHOLOGY

RHAGLEN SEICOLEG GLINIGOL GOGLEDD CYMRU
NORTH WALES CLINICAL PSYCHOLOGY PROGRAMME

PRIFYSGOL BANGOR UNIVERSITY

TAFLEN WYBODAETH I BERSON IFANC

Cyfeirnod REC: 16/WA/0025

Astudiaeth ar y ffordd orau o gefnogi pobl ifanc sy'n cael Therapi Ymddygiad Dialectig (DBT) a'u Rhieni/Gofalwyr.

Gwybodaeth am yr ymchwil

Rydym o Brifysgol Bangor a Bwrdd Iechyd Prifysgol Betsi Cadwaladr ac rydym yn gofyn i chi gymryd rhan yn ein hastudiaeth ymchwil. Dim ond os ydych chi eisiau cymryd rhan y dylech chi wneud hynny. Cyn i chi benderfynu cymryd rhan neu beidio, mae'n bwysig eich bod yn deall pam rydym yn cynnal yr ymchwil hwn, a beth fyddai cymryd rhan yn ei olygu i chi.

Cymerwch amser i ddarllen y wybodaeth ar y daflen hon yn ofalus a'i thrafod gydag eraill os dymunwch. Bydd y Swyddog Ymchwil, Victoria Garvey, yn cysylltu â chi ar ôl ichi dderbyn y daflen hon a gallwch ei holi hi os oes rhywbeth yn aneglur neu os hoffech gael rhagor o wybodaeth.

Tîm ymchwil

Dr Michaela Swales, Seicolegydd Clinigol (BIPBC)

Yr Athro Jonathan Hill, Athro Seiciatreg Plant a'r Glasoed (Prifysgol Reading)

Dr Mike Jackson, Seicolegydd Clinigol (BIPBC)

Stefania Pethica, Seicolegydd Clinigol dan Hyfforddiant (BIPBC, Prifysgol Bangor)

Victoria Garvey, Swyddog Ymchwil (BIPBC)

Katy Jones, Cynorthwyydd Ymchwil (BIPBC)

Beth yw pwrpas yr astudiaeth?

Nod yr astudiaeth hon yw canfod y ffyrdd gorau o asesu canlyniadau Therapi Ymddygiad Dialectig (DBT), a chanfod sut i gefnogi rhieni/gofalwyr pobl ifanc fel chi sy'n cael Therapi Ymddygiad Dialectig.

Byddwn yn canfod y ffordd orau o asesu a yw DBT yn gweithio drwy ofyn ichi lenwi dau holiadur, cymryd rhan mewn dau gyfweliad ac ymgymryd â thasg ddatrys problemau cyn ichi ddechrau DBT ac ar ddiwedd eich therapi.

Gofynnir i'ch rhiant/gofalwr hefyd gymryd rhan mewn cyfweliadau os ydynt yn cydsynio i gymryd rhan yn yr astudiaeth hon. Byddant hefyd yn cael cynnig Therapi Meysydd Teulu (FDT), ymyrraeth newydd i rieni/gofalwyr pobl ifanc sydd wedi'u cyfeirio at Therapi Ymddygiad Dialectig.

Pam rydw i wedi cael gwahoddiad i gymryd rhan?

Rydym yn gwahodd pob person ifanc sydd wedi cael eu cyfeirio at Therapi Ymddygiad Dialectig yng ngogledd Cymru a'u rhieni/gofalwyr.

Oes rhaid imi gymryd rhan?

Chi sy'n dewis a ydych am gymryd rhan ai peidio. Nid oes rhaid i chi gymryd rhan. Chi sydd i benderfynu hynny. Dylech ddarllen y daflen wybodaeth hon ac os oes gennych unrhyw gwestiynau dylech holi Victoria, y Swyddog Ymchwil, pan ddaw hi i gwrdd â chi. Gallwch ddweud na nawr, neu gallwch hyd yn oed newid eich meddwl yn nes ymlaen. Nid oes raid ichi roi rheswm dros roi'r gorau iddi. Ni fyddwch yn pechu neb os penderfynwch beidio cymryd rhan yn yr astudiaeth hon.

Beth ydych chi'n gofyn i mi ei wneud?

Os byddwch yn penderfynu cymryd rhan byddwn yn gofyn i chi lofnodi ffurflen gydsynio. Bydd Victoria wedyn yn trafod trefn yr ymchwil gyda chi.

1. Yn gyntaf, byddwch yn trefnu i gyfarfod ein Cynorthwyydd Ymchwil yn rhywle preifat (am resymau cyfrinachedd) yn eich Gwasanaethau Iechyd Meddwl Plant a'r Glasoed lleol. Yn ystod y cyfarfod hwn bydd y Cynorthwyydd Ymchwil yn rhoi 2 holiadur ichi eu llenwi. Bydd y Cynorthwyydd Ymchwil wedyn yn eich cyfweld ynglŷn â'r problemau rydych wedi bod yn eu cael sydd wedi golygu eich bod yn cael DBT. Bydd y cyfarfod hwn yn cymryd tuag awr a hanner i gyd, ond, gallwch wastad stopio os ydych yn gweld y cyfweliad yn rhy hir, a pharhau ag ef mewn cyfarfod arall.

2. Yn ail, gofynnir ichi wneud asesiad datrys problemau. Mae DBT yn ceisio helpu pobl ifanc drwy wella eu sgiliau datrys problemau, a dyna pam rydym yn gofyn ichi wneud hyn,

er mwyn gweld a yw DBT yn eich helpu gyda hyn hefyd. Byddwn yn gofyn ichi ddod â'ch rhiant/gofalwr i'r asesiad hwn fel eu bod yno i'ch helpu os hoffech gael eu cymorth nhw. Bydd yr asesiad hwn yn cael ei recordio ar fideo.

3. Yn olaf, ar ôl ichi orffen DBT, bydd y Cynorthwyydd Ymchwil yn cysylltu â chi eto ac yn gofyn ichi wneud y pethau hyn i gyd eto. Gwneir hyn fel y gallwn weld o ddifrif pa mor dda mae DBT yn gweithio.

Bydd pob cyfweliad yn cael ei recordio. Bydd yr holl recordiadau o ddata ar offer sain yn cael eu dileu ar ôl i ni eu trawsgrifio. Hyd yn oed os ydych wedi penderfynu cymryd rhan, mae gennych hawl o hyd i roi'r gorau iddi ar unrhyw adeg yn ystod y cyfarfodydd gyda'r Cynorthwyydd Ymchwil.

Beth os nad ydw i eisiau cymryd rhan?

Chi sy'n dewis a ydych am gymryd rhan ai peidio. Ni fydd penderfynu peidio â chymryd rhan yn effeithio ar unrhyw agwedd ar eich triniaeth na'ch perthynas gyda'ch therapydd.

Pwy sy'n mynd i wybod fy mod i'n cymryd rhan yn y gwaith ymchwil hwn?

Dim ond clinigwyr CAMHS y person ifanc a'ch meddyg teulu fydd yn gwybod eich bod chi'n cymryd rhan yn y gwaith ymchwil. Byddwn yn rhoi gwybod i'ch meddyg teulu trwy anfon llythyr ato. Byddwn yn dweud wrth feddygon teulu fel ei fod yn gwybod pa driniaeth rydych yn ei chael.

Yr laith Gymraeg

Darperir gwybodaeth am yr astudiaeth yn ddwyieithog. Yn anffodus, cynhelir yr holl gyfweliadau ymchwil yn Saesneg. Rydym yn gwneud hyn er mwyn cynnal cysondeb yn y data rydym yn eu casglu, sy'n bwysig ar gyfer ein hymchwil. Ond, gallwch gael DBT yn Gymraeg os hoffech chi - siaradwch gyda'ch therapydd DBT.

Beth yw'r buddion a'r peryglon posibl o gymryd rhan?

Bydd yr wybodaeth a gawn o'r astudiaeth yn ein helpu i wybod sut i benderfynu ar y ffordd orau o fesur pa mor dda mae DBT yn gweithio a sut hefyd i gefnogi pobl ifanc fel chi a'u rhieni/gofalwyr. Trwy gymryd rhan yn yr ymchwil hwn byddwch yn helpu i ddatblygu gwasanaethau i bobl ifanc a'u rhieni/gofalwyr. Yn ogystal, byddwn yn darparu crynodeb ichi o'r adroddiad terfynol yn disgrifio beth rydym wedi ei ganfod drwy wneud yr ymchwil.

Y prif berygl wrth gymryd rhan yn yr astudiaeth hon yw y gallai ateb holiaduron a chymryd rhan mewn cyfweliadau ddod ag emosiynau anghyfforddus i'r wyneb. Fodd bynnag, mae llawer o bobl ifanc yn gweld bod y sgyrsiau hyn yn gallu bod yn fuddiol hefyd oherwydd yn

ystod y cyfweliadau gallwch egluro'ch safbwynt ar yr anawsterau rydych wedi'u profi gartref neu yn yr ysgol. Mae pob aelod o'r tîm ymchwil wedi cael eu hyfforddi ar sut i gynnal cyfweliadau o'r fath a gallwch stopio'r cyfweliad ar unrhyw adeg heb roi rheswm os ydych yn teimlo'n rhy anghysurus.

A fydd fy nghyfraniad yn cael ei gadw'n gyfrinachol?

Mae beth a ddywedwch yn y cyfweliadau a'r holiaduron rydych yn eu llenwi yn gyfan gwbl gyfrinachol a chedwir hynny'n ddiogel hyd nes y bydd yr ymchwil wedi'i orffen. Bydd gwybodaeth bersonol yn cael ei thynnu allan o'r holl ddata fydd yn cael eu dadansoddi. Mae hyn yn golygu na fyddwn byth yn datgelu enwau unrhyw un a fu'n cymryd rhan. Ni fydd unrhyw bosibilrwydd y gellid eich cysylltu chi fel unigolyn gyda'r data ar unrhyw adeg.

Fodd bynnag, os byddwch chi'n dweud wrth un o'r ymchwilwyr eich bod chi neu rywun arall mewn perygl o gael niwed difrifol bydd rhaid i'r ymchwilydd gysylltu gyda'ch therapydd DBT a rhoi gwybod iddyn nhw eu bod yn meddwl eich bod chi neu rywun arall mewn perygl.

Bydd Deddf Diogelu Data 1998 y DU yn berthnasol i'r holl wybodaeth a roddwch i ni yn y cyfweliadau. Cedwir yr wybodaeth ar ffeiliau cyfrifiadurol y mae angen cyfrinair er mwyn cael atynt ac mewn cypyrddau wedi eu cloi ym Mwrdd Iechyd Prifysgol Betsi Cadwaladr. Ni chaiff neb ar wahân i'r tîm ymchwil fynediad at y data; a chedwir anhysbysrwydd y deunydd drwy ddefnyddio enwau ffug. Ni fydd posib cysylltu unrhyw ddata gydag unrhyw unigolyn sy'n cymryd rhan yn yr astudiaeth hon.

Sut mae'r project yn cael ei gyllido?

Cyllidir y project gan Fwrdd Iechyd Prifysgol Betsi Cadwaladr.

Beth fydd yn digwydd i ganlyniadau'r astudiaeth?

Byddwn yn ysgrifennu adroddiad yn crynhoi prif ganfyddiadau'r astudiaeth, ac yn anfon copi ohono atoch. Rydym hefyd yn bwriadu lledaenu canfyddiadau'r ymchwil drwy gyhoeddiadau a chynadleddau.

Gyda phwy ddylwn i gysylltu i gael mwy o wybodaeth?

Os oes gennych unrhyw gwestiynau neu os hoffech gael rhagor o wybodaeth am yr astudiaeth hon, cysylltwch â Victoria Garvey neu Dr Michaela Swales gan ddefnyddio'r manylion cysylltu isod:

Victoria Garvey Swyddog Ymchwil Bwrdd Iechyd Prifysgol Betsi Cadwaladr Ysgol Gwyddorau Meddygol Prifysgol Bangor BANGOR LL57 2AS Ffôn: +44 (0)1248 383615 E-bost: Victoria.Garvey@wales.nhs.uk	Dr Michaela Swales Rhaglen Seicoleg Glinigol Gogledd Cymru Ysgol Seicoleg Prifysgol Bangor BANGOR LL57 2DG Ffôn: +44 (0)1248 382552 E-bost: m.swales@bangor.ac.uk

Beth os aiff rhywbeth o'i le?

Os yw'r astudiaeth hon wedi'ch niweidio chi neu'ch person ifanc mewn unrhyw ffordd neu os ydych yn dymuno gwneud cwyn am y ffordd y mae'r astudiaeth yn cael ei chynnal, dyma bobl y gallwch gysylltu â nhw am ragor o gyngor a gwybodaeth:

Ysgol Seicoleg - Pennaeth yr Ysgol	Ysgol Seicoleg - Rheolwr yr Ysgol
Yr Athro John Parkingson Adeilad Brigantia Ffordd Penrallt Gwynedd LL57 2AS Y Deyrnas Unedig Ffôn: +44 (0)1248 38 2211 Ffacs: +44 (0)1248 38 2599 E-bost: j.parkinson@bangor.ac.uk	Mr Hefin Francis Adeilad Brigantia Ffordd Penrallt Gwynedd LL57 2AS Y Deyrnas Unedig Ffôn: +44 (0) 1248 388339 Ffacs: +44 (0) 1248 38 2599 E-bost:h.francis@bangor.ac.uk

Diolch i chi am ddarllen y daflen wybodaeth hon ac am ystyried cymryd rhan yn yr astudiaeth.

ETHICS APPENDIX XIII

Information Sheet for Parent/Carer

COLEG IECHYD A GWYDDORAU YMDDYGIAD
COLLEGE OF HEALTH & BEHAVIOURAL SCIENCES

YSGOL SEICOLEG
SCHOOL OF PSYCHOLOGY

RHAGLEN SEICOLEG CLINIGOL GOGLEDD CYMRU
NORTH WALES CLINICAL PSYCHOLOGY PROGRAMME

PRIFYSGOL BANGOR UNIVERSITY

INFORMATION SHEET FOR PARENTS/CARERS'

REC Reference Number:16/WA/0025

A study on how best to support young people going through DBT and their Parents/Carers.

Information about the research

We would like to invite you and your young person to participate in this research project which is being carried out across Betsi Cadwaladr University Health Board (BCUHB). You and your young person should only participate if you want to. Before you decide whether you and your young person want to take part, it is important for you to understand why the research is being done and what your participation and your young person's participation will involve.

Please take time to read the following information carefully and discuss it with others if you wish. Victoria Garvey, our Research Officer, will be in touch with you after you have received this sheet and you can ask her if there is anything that is not clear or if you would like more information.

If you choose to participate we will monitor your young person's progress in DBT closely and you will have the opportunity to take part in a new form of therapy called Family Domains Therapy (FDT), which is aimed at supporting the parents/carers of young people who have been referred for DBT. You should receive an information sheet about FDT together with this information sheet. If you choose not to participate you will still be able to access routinely available support at your local CAMHS service, your young person's treatment will not be affected in any way.

Research team

Dr Michaela Swales, Clinical Psychologist (BCUHB)

Prof Jonathan Hill, Professor of Child and Adolescent Psychiatry (University of Reading)

Dr Mike Jackson, Clinical Psychologist (BCUHB)

Stefania Pethica, Trainee Clinical Psychologist (BCUHB, Bangor University)

Victoria Garvey, Research Officer (BCUHB)

Katy Jones, Research Assistant (BCUHB)

What is the purpose of the study?

The aim of this study is to provide a better understanding of how to support the parents/carers of young people who are receiving DBT. With regards to parents/carers, we are interested in how parents/carers are feeling when their young person receives DBT (e.g. parents/carers wellbeing).

Parents and carers whose young people have attended DBT in the past told us that they needed more help and support in how to help their young person. For this reason, as part of the study, we will also be offering parents/carers the possibility to take part in a new intervention called Family Domains Therapy (FDT), which aims to support parents. You can choose if you want to take part in FDT, or not, at any point of your young person's treatment. We are specifically interested in understanding how parents/carers choose whether they want to take part in FDT or not, and whether they find FDT helpful if they do.

This will all be done by asking you to fill in some questionnaires and take part in an interview at the end of your young person's treatment. Your young person will be asked to take part in two interviews and fill in two questionnaires at the start and end of their treatment. You will both be asked to take part in a task together.

Why have we been invited to take part?

We are inviting all young people who have been referred for DBT and their parents/carers in North Wales.

Do I have to take part?

Participation is voluntary. You and your young person do not have to take part. You should read this information sheet and if you have any questions you should ask Victoria Garvey, Research Officer, when she comes to meet you. If you do consent to participate and for your young person to participate in the research, you and your young person can decide not to take part at any point during the study without giving a reason if you no longer wish to participate.

What will happen to me if I take part?

If you decide to take part you will be asked to sign a consent form. Victoria Garvey will then discuss the research procedure with you.

1. Firstly, the Research Assistant will arrange to meet you in a private place (for confidentiality reasons) at your home or at your local CAMHS. During this meeting you will be asked to fill in 5 questionnaires and asked to talk about your young person for 5 minutes (this part will be audio-recorded). This will take approximately half an hour.

2. Secondly, you will be asked to join your young person for one assessment of your young person's problem solving skills. During this assessment you will be asked to just be available if your young person wants your help to complete the task. This assessment will be video recorded.

3. Thirdly, while your young person receives DBT, you will have the opportunity to take part in a new supportive family intervention called Family Domains Therapy (FDT), which is aimed to assist parents/carers of young people referred for DBT. You don't have to take

part in FDT. Participation is voluntary. If you do take part, you will be asked to complete a short questionnaire at the end of each session to tell us what you found helpful or not about the therapy and the therapy sessions will be video-recorded for training and research purposes.

4. Finally, a research team member will contact you at the end of your young person's treatment to arrange a meeting in a private place (for confidentiality reasons) at your home or at your local CAMHS. You will be asked to fill in the same 5 questionnaires that you filled in at the start and you will be interviewed about your young person, why you chose to take part in FDT or not and what you found helpful or not about it. This second meeting will last approximately 1 hour to one and a half hours.

All interviews will be recorded. All data will be stored safely and confidentially. All recordings of data on audio-equipment will be deleted after transcription. Even if you have decided to take part, you are still free to stop your participation at any time during meetings with members of the research team.

What will happen to my young person if I consent to them taking part?

If you consent to your young person taking part in the research the Research Assistant will get in touch with them and take them through this research procedure.

1. Firstly, your young person will arrange to meet with the Research Assistant in a private place (for confidentiality reasons) at your local CAMHS. During this meeting the Research Assistant will give your young person 2 questionnaires to fill in. The Research Assistant will then interview your young person about the problems that have led to their referral to DBT. This meeting will be approximately 1 hour and a half long, however, your young person can always ask to stop if they find it too long and continue it in another meeting.

2. Secondly, you and your young person will be asked to do a problem-solving assessment, as mentioned above.

3. Finally, after your young person has finished DBT, the Research Assistant will get back in touch with them and they will be asked to do the questionnaires, interviews and problem solving task again. This will help us understand how to evaluate DBT.

What will happen to me or my young person if we do not want to take part?

Participation is voluntary. Deciding not to take part will not impact any aspect of your young person's treatment. It will mean that you will not be able to access FDT, the new intervention that we are trialling. However, you will be able to access the parent/carer support and/or family therapy usually available at your local CAMHS.

Who is going to know that I am taking part in this research?

Only your young person's CAMHS clinicians and your GP will know that you and your young person are taking part in this research. We will inform your GP by sending them a letter. We are going to do this so that your GP knows what treatment you and your young person are receiving.

Welsh Language

Information about the study will be provided bilingually. Unfortunately, all research interviews will be conducted through the medium of English. We are doing this to maintain a consistency in the data we collect, which is important for our research. Both DBT and FDT might be available through the medium of Welsh depending on your local CAMHS.

What are the possible benefits and risks of taking part?

The information we get from the study will help to further understand how to support young people referred for DBT and their parents/carers. By taking part in this research you and your young person will contribute to the development of services for young people and their parents/carers. If you choose to access FDT you will also participate in the shaping of a new intervention to support parents/carers of young people referred to DBT. This will help to highlight both strengths and areas for development within services relating to working with young people referred for DBT and their families. In addition, we will provide you with a summary of a final report describing the main findings.

The main risk to taking part in this study is that answering questionnaires and taking part in therapy and talking about difficult life events can bring up uncomfortable emotions both for you and your young person. However, parents/carers and young people find that these conversations can be beneficial as well as they allow them to express their point of view on the difficulties they experience. All members of the research team are trained in conducting such interviews and you and your young person can interrupt the interview at any point without giving a reason should you find it too uncomfortable.

Will our taking part be kept confidential?

What is said in the interviews and the questionnaires you and your young person fill in is regarded as strictly confidential and will be held securely until the research is finished. All data for analysis will be anonymised. In reporting on the research findings, we will not reveal the names of any participants. At all times there will be no possibility of you or your young person as individuals being linked with the data.

However, if you say to one of the researchers that you or someone else is at risk of serious harm the researcher will have to contact your young person's DBT therapist and let them know that they think you or someone else is at risk.

The UK Data Protection Act 1998 will apply to all information gathered within the interviews and held on password-locked computer files and locked cabinets within BCUHB. No data will be accessed by anyone other than the research team; and anonymity of the material will be protected by using false names. No data will be able to be linked back to any individual taking part in this study.

How is the project being funded?

The project is being funded by Betsi Cadwaladr University Health Board and Bangor University.

What will happen to the results of the study?

We will produce a final report summarising the main findings, which will be sent to you. We also plan to disseminate the research findings through publications and conferences. Part of the study will be submitted as part of Trainee Clinical Psychologist Stefania Pethica's doctoral dissertation.

Who should I contact for further information?

If you have any questions or require more information about this study, please contact Victoria Garvey, Research Officer, or Dr Michaela Swales using the following contact details:

Victoria Garvey Research Officer Betsi Cadwaladr University Health Board School of Medical Sciences Bangor University BANGOR LL57 2AS Tel: +44 (0)1248 383615 Email: Victoria.Garvey@wales.nhs.uk	Dr Michaela Swales North Wales Clinical Psychology Programme School of Psychology Bangor University BANGOR LL57 2DG Tel: +44 (0)1248 382552 Email: m.swales@bangor.ac.uk

What if something goes wrong?

If this study has harmed you or your young person in any way or if you wish to make a complaint about the conduct of the study here are some people you can using the details below for further advice and information:

School of Psychology – Head of School Prof John Parkinson Adeilad Brigantia Penrallt Road Gwynedd LL57 2AS United Kingdom Tel: +44 (0)1248 38 2211 Fax: +44 (0)1248 38 2599 Email: j.parkinson@bangor.ac.uk	School of Psychology - School Manager Mr Hefin Francis Adeilad Brigantia Penrallt Road Gwynedd LL57 2AS United Kingdom Tel: +44 (0) 1248 388339 Fax: +44 (0) 1248 38 2599 Email: h.francis@bangor.ac.uk

Thank you for reading this information sheet and for considering taking part in this research.

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RHAGLEN SEICOLEG GLINIGOL GOGLEDD CYMRU
NORTH WALES CLINICAL PSYCHOLOGY PROGRAMME

TAFLEN WYBODAETH I RIENI/GOFALWYR

Cyfeirnod REC: 16/WA/0025

Astudiaeth ar y ffordd orau o gefnogi pobl ifanc sy'n cael Therapi Ymddygiad Dialectig (DBT) a'u Rhieni/Gofalwyr.

Gwybodaeth am yr ymchwil

Hoffem eich gwahodd chi a'ch person ifanc i gymryd rhan yn y project ymchwil hwn sy'n cael ei gynnal ar draws Bwrdd Iechyd Prifysgol Betsi Cadwaladr (BIPBC). Dim ond os ydych chi eisiau cymryd rhan y dylech chi a'ch person ifanc wneud hynny. Cyn ichi benderfynu a ydych chi a'ch person ifanc eisiau cymryd rhan, mae'n bwysig eich bod yn deall pam fod yr ymchwil yn cael ei gynnal a beth fydd eich cyfranogiad chi a chyfranogiad eich person ifanc yn ei olygu.

Cymerwch amser i ddarllen y wybodaeth isod yn ofalus a'i thrafod ag eraill, os dymunwch. Bydd Victoria Garvey, ein Swyddog Ymchwil, yn cysylltu â chi ar ôl ichi dderbyn y daflen hon a gallwch ei holi hi os oes rhywbeth yn aneglur neu os hoffech gael rhagor o wybodaeth.

Os byddwch yn dewis cymryd rhan byddwn yn monitro cynnydd eich person ifanc mewn Therapi Ymddygiad Dialectig yn ofalus a byddwch yn cael y cyfle i gymryd rhan mewn math newydd o therapi o'r enw Therapi Meysydd Teulu (FDT) sy'n cefnogi rhieni/gofalwyr pobl ifanc sydd wedi'u cyfeirio at Therapi Ymddygiad Dialectig. Dylech dderbyn taflen wybodaeth am Therapi Meysydd Teulu gyda'r daflen wybodaeth hon. Os byddwch yn penderfynu peidio cymryd rhan byddwch yn dal i gael mynediad at y gefnogaeth arferol yn eich Gwasanaeth Iechyd Meddwl Plant a'r Glasoed lleol ac ni fydd triniaeth eich person ifanc yn cael ei heffeithio mewn unrhyw ffordd.

Tîm Ymchwil

Dr Michaela Swales, Seicolegydd Clinigol (BIPBC)

Yr Athro Jonathan Hill, Athro Seiciatreg Plant a'r Glasoed (Prifysgol Reading)

Dr Mike Jackson, Seicolegydd Clinigol (BIPBC)

Stefania Pethica, Seicolegydd Clinigol dan Hyfforddiant (BIPBC, Prifysgol Bangor)

Victoria Garvey, Swyddog Ymchwil (BIPBC)

Katy Jones, Cynorthwyydd Ymchwil (BIPBC)

Beth yw diben yr astudiaeth?

Amcan yr astudiaeth hon yw darparu gwell dealltwriaeth o sut i gefnogi rhieni/gofalwyr pobl ifanc sy'n cael Therapi Ymddygiad Dialectig. O safbwynt rhieni/gofalwyr, mae gennym ddiddordeb yn sut mae rhieni/gofalwyr yn teimlo pan mae eu person ifanc yn cael Therapi Ymddygiad Dialectig (e.e. lles rhieni/gofalwyr).

Mae rhieni a gofalwyr y mae eu pobl ifanc wedi bod yn cael Therapi Ymddygiad Dialectig yn y gorffennol wedi dweud wrthym fod angen mwy o help a chefnogaeth arnynt i helpu eu person ifanc. Oherwydd hyn, fel rhan o'r astudiaeth, byddwn hefyd yn cynnig i rieni/gofalwyr y posibilrwydd o gymryd rhan mewn ymyrraeth newydd o'r enw Therapi Meysydd Teulu (FDT), sy'n ceisio cefnogi rhieni. Gallwch ddewis cymryd rhan yn y Therapi Meysydd Teulu, neu beidio, ar unrhyw adeg yn ystod triniaeth eich person ifanc. Mae gennym ddiddordeb penodol mewn deall sut mae rhieni/gofalwyr yn dewis a ydynt eisiau cymryd rhan mewn Therapi Meysydd Teulu neu beidio, ac os ydynt yn dewis cymryd rhan, a ydynt yn gweld Therapi Meysydd Teulu'n ddefnyddiol ai peidio.

Gwneir hyn drwy ofyn ichi lenwi holiaduron a chymryd rhan mewn cyfweliad ar ddiwedd triniaeth eich person ifanc. Gofynnir i'ch person ifanc gymryd rhan mewn dau gyfweliad a llenwi dau holiadur ar ddechrau ac ar ddiwedd eu triniaeth. Gofynnir i chi'ch dau gymryd rhan mewn tasg gyda'ch gilydd.

Pam rydym ni wedi cael gwahoddiad i gymryd rhan?

Rydym yn gwahodd pob person ifanc sydd wedi cael eu cyfeirio at Therapi Ymddygiad Dialectig yng ngogledd Cymru a'u rhieni/gofalwyr.

Oes rhaid imi gymryd rhan?

Chi sy'n dewis a ydych am gymryd rhan ai peidio. Nid oes rhaid i chi a'ch person ifanc gymryd rhan. Dylech ddarllen y daflen wybodaeth hon ac os oes gennych unrhyw gwestiynau dylech holi Victoria Garvey, Swyddog Ymchwil, pan ddaw hi i gwrdd â chi. Os ydych yn cydsynio i gymryd rhan ac i'ch person ifanc gymryd rhan yn yr ymchwil, gallwch chi a'ch person ifanc benderfynu peidio cymryd rhan ar unrhyw adeg yn ystod yr astudiaeth heb roi rheswm os nad ydych eisiau cymryd rhan mwyach.

Beth fydd yn digwydd i mi os byddaf yn cymryd rhan?

Os penderfynwch gymryd rhan, byddwn yn gofyn i chi lofnodi ffurflen gydsynio. Bydd Victoria Garvey wedyn yn trafod trefn yr ymchwil gyda chi.

1. Yn gyntaf, bydd y Cynorthwyydd Ymchwil yn trefnu i gwrdd â chi yn rhywle preifat (am resymau cyfrinachedd) yn eich cartref neu yn eich Gwasanaethau Iechyd Meddwl Plant a'r Glasoed lleol. Yn ystod y cyfarfod gofynnir ichi lenwi 5 holiadur a siarad am eich person ifanc am 5 munud (bydd y rhan hon yn cael ei recordio ar dâp sain). Bydd hyn yn cymryd tua hanner awr.

2. Yn ail, gofynnir ichi ymuno â'ch person ifanc ar gyfer un asesiad o sgiliau datrys problemau eich person ifanc. Yn ystod yr asesiad hwn bydd gofyn ichi ond fod ar gael os oes angen eich help ar eich person ifanc i gwblhau'r dasg. Bydd yr asesiad hwn yn cael ei recordio ar fideo.

3. Yn drydydd, tra bydd eich person ifanc yn cael Therapi Ymddygiad Dialectig, byddwch

yn cael y cyfle i gymryd rhan mewn ymyrraeth deuluol gefnogol newydd o'r enw Therapi Meysydd Teulu, sy'n ceisio cynorthwyo rhieni/gofalwyr pobl ifanc sy'n cael Therapi Ymddygiad Dialectig. Nid oes rhaid i chi gymryd rhan yn y Therapi Meysydd Teulu. Chi sy'n dewis a ydych am gymryd rhan ai peidio. Os byddwch yn cymryd rhan, gofynnir ichi lenwi holiadur byr ar ddiwedd pob sesiwn i ddweud wrthym beth oedd yn ddefnyddiol neu yn annefnyddiol am y therapi a bydd y sesiynau therapi'n cael eu recordio ar fideo at ddibenion hyfforddiant ac ymchwil.

4. Yn olaf, bydd aelod o'r tîm ymchwil yn cysylltu â chi ar ddiwedd triniaeth eich person ifanc i drefnu cyfarfod yn rhywle preifat (am resymau cyfrinachedd) yn eich cartref neu yn eich Gwasanaethau Iechyd Meddwl Plant a'r Glasoed Ileol. Gofynnir ichi lenwi'r un 5 holiadur a lenwyd gennych ar y dechrau a byddwch yn cael eich cyfweld ynglŷn â'ch person ifanc, pam ichi ddewis cymryd rhan yn y Therapi Meysydd Teulu neu beidio a beth oedd, yn eich barn chi, yn ddefnyddiol neu'n annefnyddiol amdano. Bydd yr ail gyfarfod hwn yn para tuag awr i awr a hanner.

Bydd pob cyfweliad yn cael ei recordio. Bydd yr holl ddata'n cael ei gadw'n ddiogel ac yn gyfrinachol. Bydd yr holl recordiadau o ddata ar offer sain yn cael eu dileu ar ôl iddynt gael eu trawsgrifio. Hyd yn oed os ydych wedi penderfynu cymryd rhan, mae gennych hawl o hyd i roi'r gorau iddi ar unrhyw adeg yn ystod cyfarfodydd gydag aelodau o'r tîm ymchwil.

Beth fydd yn digwydd i'm person ifanc os byddaf yn cydsynio iddyn nhw gymryd rhan?

Os byddwch yn cydsynio i'ch person ifanc gymryd rhan yn yr ymchwil bydd y Cynorthwyydd Ymchwil yn cysylltu â nhw ac yn eu harwain drwy drefn yr ymchwil.

1. Yn gyntaf, bydd eich person ifanc yn trefnu i gyfarfod y Cynorthwyydd Ymchwil mewn lle preifat (am resymau cyfrinachedd) yn eich Gwasanaethau Iechyd Meddwl Plant a'r Glasoed Ileol. Yn ystod y cyfarfod hwn bydd y Cynorthwyydd Ymchwil yn rhoi 2 holiadur i'ch person ifanc eu llenwi. Bydd y Cynorthwyydd Ymchwil wedyn yn cyfweld eich person ifanc ynglŷn â'r problemau a arweiniodd atynt yn cael eu cyfeirio at Therapi Ymddygiad Dialectig. Bydd y cyfarfod hwn yn cymryd tuag awr a hanner i gyd, ond, gall eich person ifanc ofyn am gael rhoi'r gorau iddi os ydynt yn gweld y cyfweliad yn rhy hir, a pharhau ag ef mewn cyfarfod arall.

2. Yn ail, gofynnir i chi a'ch person ifanc wneud asesiad datrys problemau, fel y soniwyd uchod.

3. Yn olaf, ar ôl i'ch person ifanc orffen Therapi Ymddygiad Dialectig, bydd y Cynorthwyydd Ymchwil yn cysylltu â nhw unwaith eto ac yn gofyn iddynt wneud yr holiaduron, y cyfweliadau a'r dasg ddatrys problemau eto. Bydd hyn yn ein helpu ni i ddeall sut i werthuso Therapi Ymddygiad Dialectig.

Beth fydd yn digwydd i mi neu i fy mherson ifanc os nad ydym eisiau cymryd rhan?

Chi sy'n dewis a ydych am gymryd rhan ai peidio. Ni fydd penderfynu peidio cymryd rhan yn effeithio ar unrhyw agwedd ar driniaeth eich person ifanc. Bydd yn golygu na fyddwch yn gallu cael mynediad at Therapi Meysydd Teulu, ymyrraeth newydd yr ydym yn ei threialu. Fodd bynnag, byddwch yn gallu cael mynediad at y gwasanaethau cefnogi rhieni/gofalwyr a/neu therapi teulu sydd fel arfer ar gael yn eich Gwasanaethau Iechyd Meddwl Plant a'r Glasoed Ileol.

Pwy sy'n mynd i wybod fy mod i'n cymryd rhan yn y gwaith ymchwil hwn?

Dim ond clinigwyr CAMHS y person ifanc a'ch meddyg teulu fydd yn gwybod eich bod chi a'ch person ifanc yn cymryd rhan yn y gwaith ymchwil. Byddwn yn rhoi gwybod i'ch meddyg teulu trwy anfon llythyr ato. Gwnawn hyn fel bod eich meddyg teulu yn gwybod pa driniaeth rydych chi a'ch person ifanc yn ei chael.

Yr Iaith Gymraeg

Darperir gwybodaeth am yr astudiaeth yn ddwyieithog. Yn anffodus, cynhelir yr holl gyfweliadau ymchwil drwy gyfrwng y Saesneg. Rydym yn gwneud hyn er mwyn cynnal cysondeb yn y data rydym yn eu casglu, sy'n bwysig ar gyfer ein hymchwil. Efallai y bydd Therapi Ymddygiad Dialectig a Therapi Meysydd Teulu ar gael drwy gyfrwng y Gymraeg yn dibynnu ar eich Gwasanaethau Iechyd Meddwl Plant a'r Glasoed Ileol.

Beth yw'r buddion a'r peryglon posibl o gymryd rhan?

Bydd yr wybodaeth a gawn o'r astudiaeth yn help inni ddeall yn well sut i gefnogi pobl ifanc sy'n cael Therapi Ymddygiad Dialectig (DBT) a'u rhieni/gofalwyr. Trwy gymryd rhan yn yr ymchwil hwn byddwch chi a'ch person ifanc yn cyfrannu at ddatblygu gwasanaethau i bobl ifanc a'u rhieni/gofalwyr. Os byddwch yn dewis cael mynediad at Therapi Meysydd Teulu byddwch hefyd yn cymryd rhan wrth siapio ymyrraeth newydd i gefnogi rhieni/gofalwyr pobl ifanc sydd wedi'u cyfeirio at Therapi Ymddygiad Dialectig. Bydd hyn yn helpu i dynnu sylw at y cryfderau a'r meysydd sydd angen eu datblygu yn y gwasanaethau sy'n ymwneud â gweithio gyda phobl ifanc sydd wedi'u cyfeirio at Therapi Ymddygiad Dialectig a'u teuluoedd. Yn ogystal, byddwn yn darparu crynodeb o'r adroddiad terfynol yn disgrifio'r prif ganfyddiadau i chi.

Y prif risg wrth gymryd rhan yn yr astudiaeth hon yw y gallai ateb holiaduron a chymryd rhan mewn therapi a siarad am ddigwyddiadau anodd yn eich bywyd ddod ag emosiynau anghyfforddus i'r wyneb i chi a'ch person ifanc. Fodd bynnag, mae rhieni/gofalwyr a phobl ifanc yn canfod fod y sgyrsiau hyn yn gallu bod yn fuddiol hefyd gan eu bod yn eu galluogi i fynegi'u safbwyntiau ar yr anawsterau y maent yn eu profi. Mae pob aelod o'r tîm ymchwil wedi cael eu hyfforddi sut i gynnal cyfweliadau o'r fath a gallwch chi a'ch person ifanc dorri ar draws y cyfweliad ar unrhyw adeg a heb roi rheswm os ydych yn teimlo'n rhy anghysurus.

A fydd y ffaith fy mod i wedi cymryd rhan yn cael ei gadw'n gyfrinachol?

Mae beth sy'n cael ei ddweud yn y cyfweliadau a'r holiaduron yr ydych chi a'ch person ifanc yn eu llenwi yn cael ei ystyried yn gyfan gwbl gyfrinachol a chaiff ei gadw'n ddiogel hyd nes y bydd yr ymchwil wedi'i orffen. Bydd gwybodaeth bersonol yn cael ei thynnu o'r holl ddata fydd yn cael eu dadansoddi. Wrth adrodd am ganfyddiadau'r ymchwil, ni fyddwn yn datgelu enwau unrhyw un a fu'n cymryd rhan. Ni fydd unrhyw bosibilrwydd y gellid eich cysylltu chi na'ch person ifanc gyda'r data ar unrhyw adeg.

Fodd bynnag, os byddwch chi'n dweud wrth un o'r ymchwilwyr eich bod chi neu rywun arall mewn perygl o gael niwed difrifol bydd rhaid i'r ymchwilydd gysylltu gyda Therapydd Ymddygiad Dialectig eich person ifanc a rhoi gwybod iddyn nhw eu bod yn meddwl eich bod chi neu rywun arall mewn perygl.

Bydd Deddf Diogelu Data 1998 y DU yn berthnasol i'r holl wybodaeth a gesglir yn y cyfweliadau a bydd yr wybodaeth yn cael ei chadw ar ffeiliau cyfrifiadurol y mae angen cyfrinair er mwyn cael atynt ac mewn cypyrddau wedi eu cloi ym Mwrdd Iechyd Prifysgol Betsi Cadwaladr. Ni chaiff neb ar wahân i'r tîm ymchwil fynediad at y data; a chedwir anysbysrwydd y deunydd drwy ddefnyddio enwau ffug. Ni fydd posib cysylltu unrhyw ddata gydag unrhyw unigolyn sy'n cymryd rhan yn yr astudiaeth hon.

Sut mae'r project yn cael ei gyllido?

Cyllidir y project gan Fwrdd Iechyd Prifysgol Betsi Cadwaladr a Phrifysgol Bangor.

Beth fydd yn digwydd i ganlyniadau'r astudiaeth?

Byddwn yn cynhyrchu adroddiad terfynol yn crynhoi'r prif ganfyddiadau, ac yn anfon copi ohono atoch. Rydym hefyd yn bwriadu lledaenu canfyddiadau'r ymchwil drwy gyhoeddiadau a chynadleddau. Cyflwynir rhan o'r astudiaeth fel rhan o draethawd doethurol Seicolegydd Clinigol dan Hyfforddiant Stefania Pethica.

Gyda phwy ddylwn i gysylltu i gael mwy o wybodaeth?

Os oes gennych unrhyw gwestiynau neu os hoffech gael rhagor o wybodaeth am yr astudiaeth hon, cysylltwch â Victoria Garvey, Swyddog Ymchwil, neu Dr Michaela Swales gan ddefnyddio'r manylion cysylltu isod:

Victoria Garvey Swyddog Ymchwil Bwrdd Iechyd Prifysgol Betsi Cadwaladr Ysgol Gwyddorau Meddygol Prifysgol Bangor BANGOR LL57 2AS Ffôn: +44 (0)1248 383615 E-bost: Victoria.Garvey@wales.nhs.uk	Dr Michaela Swales Rhaglen Seicoleg Glinigol Gogledd Cymru Ysgol Seicoleg Prifysgol Bangor BANGOR LL57 2DG Ffôn: +44 (0)1248 382552 E-bost: m.swales@bangor.ac.uk

Beth os aiff rhywbeth o'i le?

Os yw'r astudiaeth hon wedi'ch niweidio chi neu'ch person ifanc mewn unrhyw ffordd neu os ydych yn dymuno gwneud cwyn am y ffordd y mae'r astudiaeth yn cael ei chynnal, dyma bobl y gallwch gysylltu â nhw am ragor o gyngor a gwybodaeth:

Ysgol Seicoleg - Pennaeth yr Ysgol Yr Athro John Parkingson Adeilad Brigantia Ffordd Penrallt Gwynedd LL57 2AS Y Deyrnas Unedig Ffôn: +44 (0)1248 38 2211 Ffacs: +44 (0)1248 38 2599 E-bost: j.parkinson@bangor.ac.uk	Ysgol Seicoleg - Rheolwr yr Ysgol Mr Hefin Francis Adeilad Brigantia Ffordd Penrallt Gwynedd LL57 2AS Y Deyrnas Unedig Ffôn: +44 (0) 1248 388339 Ffacs: +44 (0) 1248 38 2599 E-bost:h.francis@bangor.ac.uk

Diolch i chi am ddarllen y daflen wybodaeth hon ac am ystyried cymryd rhan yn yr ymchwil hwn.

ETHICS APPENDIX XIV

Information Sheet on Family Domains Therapy

COLEG IECHYD A GWYDDORAU YMDDYGIAD
COLLEGE OF HEALTH & BEHAVIOURAL SCIENCES

YSGOL SEICOLEG
SCHOOL OF PSYCHOLOGY

PRIFYSGOL BANGOR UNIVERSITY

RHAGLEN SEICOLEG CLINIGOL GOGLEDD CYMRU
NORTH WALES CLINICAL PSYCHOLOGY PROGRAMME

WHAT IS FAMILY DOMAINS THERAPY?

Why am I being offered Family Domains Therapy?

Parenting is one of the hardest things to do, and no-one is a "perfect parent" or a "perfect child" or a "perfect young person". It can be very challenging and becomes more challenging when a child or young person develops a mental health problem.

Whilst we don't always know why a child or young person may become unwell, we do have ways to help them and their family. Family Domains Therapy has been designed to support parents make sense of worrying and confusing interactions with their young people.

As part of this research project you will be offered 10 session of Family Domains Therapy (but you can review the length of therapy with your family therapist).

What is Family Domains Therapy?

Family Domains Therapy is a form of Family Therapy. Family Therapy can help those in close relationships to better understand and support each other.

It enables family members to express and explore difficult thoughts and emotions safely, and work together to make useful changes in their relationships and lives.

Family Domains Therapy is based on the research evidence that children look to their parents to respond to different needs: for example to be kept safe, to be comforted, to be guided, and to share.

What are "domains"?

We call "domains" the combinations of the child's needs and the parents' responses.

Child's need + Parents' response = Domain

When children signal their needs clearly, and parents respond in ways that address them, we refer to each domain being clear and matched: the parents' response matches the child's need.

When domains are clear and matched, parents and children understand what is going on, and where there are problems, they know how they are to be addressed.

When domains are unclear or unmatched, for example if the child is not signalling his or her need clearly there can be misunderstandings about what is going on, and parents and children can feel angry, hurt or upset.

Unclear or mismatched domains are part of everyday life in all families, but they can be troublesome when someone has a mental health problem that affects emotions or behaviours, or when they happen a lot leading to confusion and distress.

What does the Family Domains Therapist do?

Day-to-day interactions and conversations happen very quickly. So, it is not easy to spot what is happening in the domains: what the child needs and how to respond.

The Family Therapist will help parents slow down the action, and finding out about the details of interactions, sometimes ones that parents or children find worrying or confusing, and sometimes very ordinary ones such as what happens when a young person arrives home from school.

We can then start to see how the domains are signalled by young people and parents, how young people and parents get their needs across to each other. We might explore where there may be room for lack of clarity regarding the domain, and then what might make things clearer.

Sometimes it is useful to pause and for the therapist to explain in detail how the domains work in general, what makes them clear and matched, to provide something like a map when noticing things. Sometimes FDT is done with parents and young people together, and sometimes only with parents.

When Family Domains Therapy is offered together with Dialectical Behaviour Therapy we often spend more time with parents alone, as the young person is already in therapy, but that can be different.

How can Family Domains Therapy help me?

Things can improve in different ways depending on what we find out by tracking interactions, and depending on what parents find more useful. Sometimes parents spot alternative things that they may do, for example to help a young person to see the difference between two domains, and at other times the therapist may give advice on how that might be done. The overall aim of Family Domains Therapy is to help parents make sense of worrying and confusing interactions and generate their own solutions based on what works best for their family.

If you are interested in taking part in Family Domains Therapy you can contact your local CAMHS family therapist to arrange a meeting:

Paul Tranter Denbighshire CAMHS, Royal Alexandra Hospital Marine Drive, Rhyl LL18 3AS Tel: 01745 448670	**Steve Riley** North Wales Adolescent Service Abergele Hospital Llanfair Rd, Abergele, Conwy LL22 8DP Tel: 01745 448700	**Heather Lee** Wrexham CAMHS Wrexham Child Health Centre Wrexham Maelor Hospital Croesnewydd Road Wrexham, Clwyd LL13 7TD Tel:01978 725242

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BETH YW THERAPI MEYSYDD TEULU?

Pam ydw i'n cael cynnig Therapi Meysydd Teulu?

Mae bod yn rhiant yn un o'r pethau anoddaf i'w gwneud, ac nid oes neb yn "rhiant perffaith" neu'n "blentyn perffaith" neu'n "berson ifanc perffaith". Gall fod yn heriol iawn ac mae hyd yn oed yn fwy heriol pan mae plentyn neu berson ifanc yn datblygu problem iechyd meddwl.

Tra nad ydym wastad yn gwybod pam fod plentyn neu berson ifanc yn mynd yn wael, mae gennym wastad ffyrdd o'u helpu nhw a'u teulu. Cynlluniwyd Therapi Meysydd Teulu er mwyn helpu rhieni i wneud synnwyr o'r rhyngweithio gofidus a dryslyd gyda'u pobl ifanc.

Fel rhan o'r project ymchwil hwn byddwch yn cael cynnig 10 sesiwn o Therapi Meysydd Teulu (ond gallwch adolygu hyd y therapi gyda'ch therapydd teulu).

Beth yw Therapi Meysydd Teulu?

Math ar Therapi Teulu yw Therapi Meysydd Teulu. Gall Therapi Teulu helpu rhai sydd mewn perthynas agos i ddeall a chefnogi'i gilydd yn well.

Mae'n galluogi aelodau o deulu i fynegi ac archwilio meddyliau ac emosiynau anodd mewn ffordd ddiogel, a gweithio gyda'i gilydd i wneud newidiadau defnyddiol i'w perthynas a'u bywydau.

Mae Therapi Meysydd Teulu'n seiliedig ar dystiolaeth ymchwil fod plant yn troi at eu rheini i ymateb i wahanol anghenion: er enghraifft i gael eu cadw'n ddiogel, i gael eu cysuro, i gael arweiniad, ac i rannu.

Beth yw "meysydd"?

"Meysydd" yw beth rydym ni'n galw'r cyfuniadau o anghenion y plentyn ac ymatebion y rhieni.

Anghenion y plentyn + Ymateb y rhieni = Maes

Pan mae plant yn dangos eu hanghenion yn glir, a'r rhieni'n ymateb mewn ffyrdd sy'n mynd i'r afael â nhw, rydym yn dweud fod pob maes yn glir ac yn cyfateb: mae ymateb y rhieni'n cyfateb i anghenion y plentyn.

Pan mae meysydd yn glir ac yn cyfateb, mae rhieni a phlant yn deall beth sy'n digwydd, yn lle mae problemau, ac maent yn gwybod sut y dylid mynd i'r afael â nhw.

Pan nad yw meysydd yn glir neu'n cyfateb, er enghraifft os nad yw'r plentyn yn dangos ei anghenion yn glir, gall camddealltwriaeth ddigwydd ynglŷn â beth sy'n digwydd, a gall rhieni a phlant deimlo'n flin, wedi eu brifo neu'n ofidus.

Mae meysydd aneglur neu anghymharus yn rhan o fywyd pob dydd ym mhob teulu, ond gallant beri trafferth pan mae gan rywun broblem iechyd meddwl sy'n effeithio ar emosiynau neu ymddygiad, neu pan maent yn digwydd yn aml gan arwain at ddryswch a gofid.

Beth mae'r Therapydd Meysydd Teulu yn ei wneud?

Mae rhyngweithiadau a sgyrsiau dydd i ddydd yn digwydd yn gyflym iawn. Felly, nid yw'n hawdd gweld beth sy'n digwydd yn y meysydd: beth sydd ei angen ar y plentyn a sut i ymateb.

Bydd y Therapydd Teulu'n helpu rhieni i arafu'r gweithredu, a chanfod mwy am fanylion rhyngweithiadau, weithiau rhai sy'n peri dryswch neu ofid i rieni neu blant, ac weithiau rhai arferol iawn fel beth sy'n digwydd pan mae person ifanc yn cyrraedd adref o'r ysgol.

Gallwn wedyn ddechrau gweld sut mae pobl ifanc a rhieni'n tynnu sylw at y meysydd, a sut mae pobl ifanc a rhieni'n cyfleu eu hanghenion i'w gilydd. Efallai yr archwiliwn ble mae lle i ddiffyg eglurder parthed y maes, ac wedyn beth fyddai'n gwneud pethau'n gliriach.

Weithiau mae'n ddefnyddiol aros ac i'r therapydd egluro'n fanwl sut mae'r meysydd yn gweithio'n gyffredinol, beth sy'n eu gwneud yn glir ac yn gyfatebol, i ddarparu rhywbeth fel map wrth sylwi ar bethau. Weithiau mae Therapi Meysydd Teulu yn cael ei gynnal gyda'r rhieni a'r bobl ifanc gyda'i gilydd, ac weithiau gyda'r rhieni'n unig.

Pan mae Therapi Meysydd Teulu yn cael ei gynnig ar y cyd â Therapi Ymddygiad Dialectig rydym yn aml yn treulio mwy o amser gyda'r rhieni yn unig, gan fod y person ifanc mewn therapi eisoes, ond gall hynny fod yn wahanol.

Sut gall Therapi Meysydd Teulu fy helpu i?

Gall pethau wella mewn ffyrdd gwahanol yn dibynnu ar beth a ganfyddwn drwy olrhain rhyngweithiadau, ac yn dibynn beth mae'r rheini'n feddwl sydd fwyaf defnyddiol. Weithiau mae rhieni'n sylwi ar bethau gwahanol y gallent eu gwneud, er enghraifft helpu person ifanc i weld y gwahaniaeth rhwng dau faes, a dro arall efallai y bydd y therapydd yn rhoi cyngor ar sut y gellir gwneud hynny. Nod cyffredinol Therapi Meysydd Teulu yw helpu rhieni i wneud synnwyr o ryngweithiadau gofidus a dryslyd a chanfod eu datrysiadau eu hunain yn seiliedig ar beth sy'n gweithio orau i'w teulu nhw.

Os oes gennych ddiddordeb mewn cymryd rhan mewn Therapi Meysydd Teulu gallwch gysylltu â therapydd teulu'ch Gwasanaethau Iechyd Meddwl Plant a'r Glasoed lleol i drefnu cyfarfod:

Paul Tranter Gwasanaethau Iechyd Meddwl Plant a'r Glasoed Sir Ddinbych, Ysbyty Brenhinol Alexandra, Rhodfa'r Môr, Rhyl, LL18 3AS Ffôn: 01745 448670	**Steve Riley** Gwasanaeth Pobl Ifanc Gogledd Cymru, Ysbyty Abergele, Ffordd Llanfair, Abergele, Conwy LL22 8DP Ffôn: 01745 448700	**Heather Lee** Gwasanaeth Iechyd Meddwl Plant a Phobl Ifanc Wrecsam, Canolfan Iechyd Plant Wrecsam, Ysbyty Maelor Wrecsam, Ffordd Croesnewydd, Wrecsam, Clwyd LL13 7TD Ffôn: 01978 725242

ETHICS APPENDIX XV

Assent Form for Young Person

COLEG IECHYD A GWYDDORAU YMDDYGIAD
COLLEGE OF HEALTH & BEHAVIOURAL SCIENCES

YSGOL SEICOLEG
SCHOOL OF PSYCHOLOGY

RHAGLEN SEICOLEG CLINIGOL GOGLEDD CYMRU
NORTH WALES CLINICAL PSYCHOLOGY PROGRAMME

ASSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Study: A study on how best to support young people going through DBT and their parents/carers.

Betsi Cadwaladr University Health Board Research Ethics Committee Ref: 16/WA/0025

Thank you for considering taking part in this research. The researcher must explain the project to you before you agree to take part. If you have any questions about the Information Sheet or about the explanations already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep so you can look it up whenever you want to.

Please tick or initial

I confirm that I understand that by ticking or writing my initials in each box I am consenting to this part of the study. I understand that the researchers will think that if I leave any boxes empty it means that I DO NOT consent to that part of the study. I understand that if I don't consent to a part of the study, I might not be able to participate in the study. ☐

Please tick or initial

1. I confirm that I have read and understood the information sheet dated 02.03.2016, Version 3 for this study. I have had the opportunity to consider the information and asked questions which have been answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to drop out at any time without giving any reason. ☐
3. I consent to the researchers using my personal information for the reasons explained to me. I understand that such information will be handled in accordance with the terms of the UK Data Protection Act 1998. ☐
4. I understand that responsible individuals from Betsi Cadwaladr University Health Board might review my information for monitoring and audit purposes. (e.g. to look at how CAMHS services are working). ☐
5. I understand that my data will be kept confidential and anonymous, and it will not be possible to identify me in any publications. ☐

6. I understand that in circumstances where I or others may be at serious risk, the researcher may be obliged to inform my DBT therapist. ☐
7. I agree that the research team may use my anonymized data for future research. (In such cases, as with this project, my data would not be identifiable in any report). ☐
8. I understand that the information I give will be used in a report. This report will be published and I will receive a copy of it. ☐
9. I consent to my interviews being audio/video recorded. ☐
10. I have informed the researcher of other research I have been part of in the last year (12 months). ☐

Name of Participant	Date	Signature
Name of Researcher	Date	Signature

COLEG IECHYD A GWYDDORAU YMDDYGIAD
COLLEGE OF HEALTH & BEHAVIOURAL SCIENCES

YSGOL SEICOLEG
SCHOOL OF PSYCHOLOGY

RHAGLEN SEICOLEG GLINIGOL GOGLEDD CYMRU
NORTH WALES CLINICAL PSYCHOLOGY PROGRAMME

PRIFYSGOL BANGOR UNIVERSITY

FFURFLEN GYDSYNIO AR GYFER CYFRANOGWYR ASTUDIAETHAU YMCHWIL

Llenwch y ffurflen hon ar ôl i chi ddarllen y Daflen Wybodaeth a/neu wrando ar esboniad ynglŷn â'r ymchwil.

Teitl yr Astudiaeth: Astudiaeth ar y ffordd orau o gefnogi pobl ifanc sy'n cael Therapi Ymddygiad Dialectig (DBT) a'u rhieni/gofalwyr.

Cyfeirnod Pwyllgor Moeseg Ymchwil Bwrdd Iechyd Prifysgol Betsi Cadwaladr: 16/WA/0025

Diolch i chi am ystyried cymryd rhan yn yr ymchwil hwn. Rhaid i'r ymchwilydd egluro'r project ichi cyn ichi gytuno i gymryd rhan. Os oes gennych unrhyw gwestiynau am y Daflen Wybodaeth neu am yr esboniadau yr ydych wedi eu cael eisoes, gofynnwch i'r ymchwilydd cyn penderfynu ymuno neu beidio. Cewch gopi o'r Ffurflen Gydsynio hon i'w chadw fel y gallwch edrych arni pryd bynnag yr hoffech wneud hynny.

Ticiwch neu rhowch lythrennau blaen eich enw

Rwy'n cadarnhau fy mod yn deall fy mod, drwy dicio neu ysgrifennu llythrennau blaen fy enw ym mhob blwch, yn cydsynio i'r rhan honno o'r astudiaeth. Rwy'n deall y bydd yr ymchwilwyr yn credu, os byddaf yn gadael unrhyw flychau yn wag, bod hynny'n golygu NAD WYF yn cydsynio i'r rhan honno o'r astudiaeth. Rwy'n deall efallai na fyddaf yn gallu cymryd rhan yn yr astudiaeth os nad wyf yn cydsynio i ran o'r astudiaeth. ☐

Ticiwch neu rhowch lythrennau blaen eich enw

1. Rwy'n cadarnhau fy mod wedi darllen a deall y daflen wybodaeth ddyddiedig 02.03.2016, Fersiwn 3 ar gyfer yr astudiaeth hon. Rwyf wedi cael cyfle i ystyried y wybodaeth, a gofyn cwestiynau a chael atebion boddhaol iddynt. ☐

2. Rwy'n deall mai yn wirfoddol rwyf yn cymryd rhan a'm bod i'n rhydd i dynnu'n ôl ar unrhyw adeg, heb roi unrhyw reswm. ☐

3. Rwy'n rhoi caniatâd i'r ymchwilwyr ddefnyddio fy ngwybodaeth bersonol at y dibenion a eglurwyd imi. Deallaf y caiff gwybodaeth o'r fath ei thrin yn unol â thelerau Deddf Diogelu Data 1998. ☐

4. Rwy'n deall y gallai unigolion cyfrifol o Fwrdd Iechyd Prifysgol Betsi Cadwaladr edrych ar fy ngwybodaeth at ddibenion monitro ac archwilio. (e.e. i edrych sut mae gwasanaethau CAMHS yn gweithio). ☐

5. Rwy'n deall y cedwir fy nata'n gyfrinachol a dienw, ac na fydd posib fy adnabod mewn unrhyw gyhoeddiad. ☐

6. Rwy'n deall efallai y bydd rhaid i'r ymchwilydd roi gwybod i fy therapydd DBT mewn sefyllfaoedd lle gallwn i neu eraill fod mewn peryg difrifol. ☐

7. Rwy'n cytuno y gall y tîm ymchwil ddefnyddio fy nata dienw ar gyfer ymchwil yn y dyfodol. (Mewn achosion felly, fel gyda'r project hwn, ni fyddai posib fy adnabod o unrhyw adroddiad). ☐

8. Rwy'n deall y bydd y wybodaeth a roddaf yn cael ei defnyddio mewn adroddiad. Bydd yr adroddiad yn cael ei gyhoeddi a byddaf i'n derbyn copi ohono. ☐

9. Rwy'n caniatáu i'm cyfweliadau gael eu recordio ar dâp sain a fideo. ☐

10. Rwyf wedi rhoi gwybod i'r ymchwilydd am ymchwilion eraill rwyf wedi bod yn rhan ohonynt dros y flwyddyn (12 mis) ddiwethaf. ☐

Enw'r cyfranogwr	**Dyddiad**	**Llofnod**
Enw'r ymchwilydd	**Dyddiad**	**Llofnod**

ETHICS APPENDIX XVI

Consent Form for Parent/Carer

COLEG IECHYD A GWYDDORAU YMDDYGIAD
COLLEGE OF HEALTH & BEHAVIOURAL SCIENCES

YSGOL SEICOLEG
SCHOOL OF PSYCHOLOGY

RHAGLEN SEICOLEG CLINIGOL GOGLEDD CYMRU
NORTH WALES CLINICAL PSYCHOLOGY PROGRAMME

PRIFYSGOL BANGOR UNIVERSITY

CONSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Study: A study on how best to support young people going through DBT and their parents/carers.

Betsi Cadwaladr University Health Board Research Ethics Committee Ref: 16/WA/0025

Thank you for considering taking part in this research. The researcher must explain the project to you before you agree to take part. If you have any questions about the Information Sheet you have received or about the explanations already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

	Please tick or initial
I confirm that I understand that by ticking/initialling each box I am consenting to this element of the study. I understand that it will be assumed that unticked/initialled boxes mean that I DO NOT consent to that part of the study. I understand that by not giving consent for any one element I may be deemed ineligible for the study.	☐

	Please tick or initial
1. I confirm that I have read and understood the information sheet dated 16.12.2015, Version2 for the above study. I have had the opportunity to consider the information and asked questions which have been answered satisfactorily.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.	☐
3. I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be handled in accordance with the terms of the UK Data Protection Act 1998.	☐
4. I understand that my information may be subject to review by responsible individuals from Betsi Cadwaladr University Health Board for monitoring and audit purposes.	☐

5. I understand that confidentiality and anonymity will be maintained and it will not be possible to identify me in any publications. ☐

6. I understand that in circumstances where I or others may be at serious risk, the researcher may be obliged to inform members of the Child and Adolescent Mental Health team. ☐

7. I agree that the research team may use my anonymized data for future research. (In such cases, as with this project, data would not be identifiable in any report). ☐

8. I understand that the information I have submitted will be published as a report and part of it will be submitted as part of the Trainee Clinical Psychologist's doctoral dissertation and I will receive a copy. ☐

9. I consent to my interviews and Family Domains Therapy sessions being audio/video recorded. ☐

10. I have informed the researcher of any other research in which I am currently involved or have been involved in during the past 12 months ☐

Name of Participant	Date	Signature
Name of Researcher	Date	Signature

COLEG IECHYD A GWYDDORAU YMDDYGIAD
COLLEGE OF HEALTH & BEHAVIOURAL SCIENCES

YSGOL SEICOLEG
SCHOOL OF PSYCHOLOGY

RHAGLEN SEICOLEG GLINIGOL GOGLEDD CYMRU
NORTH WALES CLINICAL PSYCHOLOGY PROGRAMME

FFURFLEN GYDSYNIO I GYFRANOGWYR ASTUDIAETHAU YMCHWIL

Llenwch y ffurflen hon ar ôl i chi ddarllen y Daflen Wybodaeth a/neu wrando ar esboniad ynglŷn â'r ymchwil.

Teitl yr Astudiaeth: Astudiaeth ar y ffordd orau o gefnogi pobl ifanc sy'n cael Therapi Ymddygiad Dialectig (DBT) a'u rhieni/gofalwyr.

Cyfeirnod Pwyllgor Moeseg Ymchwil Bwrdd Iechyd Prifysgol Betsi Cadwaladr: 16/WA/0025

Diolch i chi am ystyried cymryd rhan yn yr ymchwil hwn. Rhaid i'r ymchwilydd egluro'r project ichi cyn ichi gytuno i gymryd rhan. Os oes gennych unrhyw gwestiynau am y Daflen Wybodaeth rydych wedi ei derbyn neu am yr esboniadau yr ydych wedi eu cael eisoes, gofynnwch i'r ymchwilydd cyn penderfynu ymuno neu beidio. Cewch gopi o'r Ffurflen Gydsynio hon i'w chadw a chyfeirio ati unrhyw bryd.

Rwy'n cadarnhau fy mod yn deall fy mod, drwy dicio neu ysgrifennu llythrennau blaen fy enw ym mhob blwch, yn cydsynio i'r elfen honno o'r astudiaeth. Rwy'n deall y cymerir yn ganiatâol y bydd unrhyw flychau heb dic neu heb lythrennau blaen fy enw yn golygu NAD WYF yn cydsynio i'r rhan honno o'r astudiaeth. Deallaf efallai na fyddaf yn cael fy ystyried yn gymwys ar gyfer yr astudiaeth os nad wyf yn cydsynio i unrhyw un elfen unigol.

Ticiwch neu rhowch lythrennau blaen eich enw

	Ticiwch neu rhowch lythrennau blaen eich enw
1. Cadarnhaf fy mod i wedi darllen a deall y daflen wybodaeth, dyddiedig 16.12.2015, Fersiwn2 ar gyfer yr astudiaeth uchod. Rwyf wedi cael cyfle i ystyried y wybodaeth, a gofyn cwestiynau a chael atebion boddhaol iddynt.	☐
2. Rydw i'n deall fy mod yn cymryd rhan yn wirfoddol ac y gallaf dynnu'n ôl unrhyw bryd, heb roi rheswm.	☐
3. Rwy'n rhoi caniatâd i fy ngwybodaeth bersonol gael ei phrosesu at y dibenion a eglurwyd imi. Deallaf y caiff gwybodaeth o'r fath ei thrin yn unol â thelerau Deddf Diogelu Data 1998.	☐
4. Rwy'n deall y gallai fy ngwybodaeth gael ei hadolygu gan unigolion cyfrifol o Fwrdd Iechyd Prifysgol Betsi Cadwaladr at ddibenion monitro ac archwilio.	☐
5. Deallaf y cedwir popeth yn gyfrinachol ac yn anhysbys ac na fydd posib fy adnabod mewn unrhyw gyhoeddiad.	☐

6. Rwy'n deall efallai y byddai'n rhaid i'r ymchwilydd roi gwybod i aelodau'r tîm Gwasanaeth Iechyd Meddwl Plant a'r Glasoed mewn sefyllfaoedd lle gallwn i neu eraill fod mewn perygl difrifol. ☐

7. Rwy'n cytuno y gall y tîm ymchwil ddefnyddio fy nata dienw ar gyfer ymchwil yn y dyfodol. (Mewn achosion felly, fel gyda'r project hwn, ni fyddai posib fy adnabod o ddata mewn unrhyw adroddiad). ☐

8. Rwy'n deall y bydd y wybodaeth rwyf i wedi'i chyflwyno yn cael ei chyhoeddi fel adroddiad ac y bydd rhan ohono'n cael ei gyflwyno fel rhan o draethawd estynedig Seicolegydd Clinigol dan Hyfforddiant ac y byddaf yn derbyn copi. ☐

9. Rwy'n caniatáu i'm cyfweliadau a'm sesiynau Therapi Meysydd Teulu gael eu recordio ar dâp sain a fideo. ☐

10. Rwyf wedi rhoi gwybod i'r ymchwilydd am unrhyw ymchwilion eraill rwyf yn cymryd rhan ynddynt neu wedi cymryd rhan ynddynt dros y 12 mis diwethaf. ☐

Enw'r cyfranogwr	**Dyddiad**	**Llofnod**
Enw'r ymchwilydd	**Dyddiad**	**Llofnod**

ETHICS APPENDIX XVII

Parental Consent form for Young Person to Participate in Research

COLEG IECHYD A GWYDDORAU YMDDYGIAD
COLLEGE OF HEALTH & BEHAVIOURAL SCIENCES

YSGOL SEICOLEG
SCHOOL OF PSYCHOLOGY

RHAGLEN SEICOLEG CLINIGOL GOGLEDD CYMRU
NORTH WALES CLINICAL PSYCHOLOGY PROGRAMME

PRIFYSGOL BANGOR UNIVERSITY

CONSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Study: A study on how best to support young people going through DBT and their parents/carers.

Betsi Cadwaladr University Health Board Research Ethics Committee Ref: 16/WA/0025

Thank you for considering allowing your young person to take part in this research. The researcher must explain the project to you before you agree for your young person to take part in it. If you have any questions about the Information Sheets you have received or about the explanations already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

	Please tick or initial
I confirm that I understand that by ticking/initialling each box I am consenting for my young person to take part in this element of the study. I understand that it will be assumed that unticked/initialled boxes mean that I DO NOT consent to that part of the study. I understand that by not giving consent for any one element I may be deemed ineligible for the study.	☐

	Please tick or initial
1. I confirm that I have read and understood the Information Sheet dated16.12.2015, Version 2 for the above study. I have had the opportunity to consider the information and asked questions which have been answered satisfactorily.	☐
2. I understand that my young person's participation is voluntary and that my young person is free to withdraw at any time without giving any reason.	☐
3. I consent to the processing of my young person's personal information for the purposes explained to me. I understand that such information will be handled in accordance with the terms of the UK Data Protection Act 1998.	☐
4. I understand that my young person's information may be subject to review by responsible individuals from Betsi Cadwaladr University Health Board for monitoring and audit purposes.	☐

5. I understand that confidentiality and anonymity will be maintained and it will not be possible to identify my young person in any publications. ☐
6. I understand that in circumstances where my young person or others may be at serious risk, the researcher may be obliged to inform members my local Child and Adolescent Mental Health Service. ☐
7. I agree that the research team may use my young person's anonymized data for future research. (In such cases, as with this project, data would not be identifiable in any report). ☐
8. I understand that the information I have submitted will be published as a report and I will receive a copy. ☐
9. I consent to my young person's interviews being audio/video recorded. ☐
10. I have informed the researcher of any other research in which my young person is currently involved or has been involved in during the past 12 months ☐

Name of Participant	Date	Signature
Name of Researcher	Date	Signature

PRIFYSGOL BANGOR UNIVERSITY

RHAGLEN SEICOLEG GLINIGOL GOGLEDD CYMRU
NORTH WALES CLINICAL PSYCHOLOGY PROGRAMME

FFURFLEN GYDSYNIO I GYFRANOGWYR ASTUDIAETHAU YMCHWIL

Llenwch y ffurflen hon ar ôl i chi ddarllen y Daflen Wybodaeth a/neu wrando ar esboniad ynglŷn â'r ymchwil.

Teitl yr Astudiaeth: Astudiaeth ar y ffordd orau o gefnogi pobl ifanc sy'n cael Therapi Ymddygiad Dialectig (DBT) a'u rhieni/gofalwyr.

Cyfeirnod Pwyllgor Moeseg Ymchwil Bwrdd Iechyd Prifysgol Betsi Cadwaladr: 16/WA/0025

Diolch i chi am ystyried gadael i'ch person ifanc gymryd rhan yn yr ymchwil hwn. Rhaid i'r ymchwilydd egluro'r project ichi cyn ichi gytuno i'ch person ifanc gymryd rhan ynddo. Os oes gennych unrhyw gwestiynau am y Daflen Wybodaeth rydych wedi ei derbyn neu am yr esboniadau yr ydych wedi eu cael eisoes, gofynnwch i'r ymchwilydd cyn penderfynu ymuno neu beidio. Cewch gopi o'r Ffurflen Gydsynio hon i'w chadw a chyfeirio ati unrhyw bryd.

Ticiwch neu rhowch lythrennau blaen eich enw

Rwy'n cadarnhau fy mod yn deall fy mod, drwy dicio neu ysgrifennu llythrennau blaen fy enw ym mhob blwch, yn rhoi caniatâd i fy mherson ifanc gymryd rhan yn yr elfen honno o'r astudiaeth. Rwy'n deall y cymerir yn ganiataol y bydd unrhyw flychau heb dic neu heb lythrennau blaen fy enw yn golygu NAD WYF yn cydsynio i'r rhan honno o'r astudiaeth. Deallaf efallai na fyddaf yn cael fy ystyried yn gymwys ar gyfer yr astudiaeth os nad wyf yn cydsynio i unrhyw un elfen unigol.

Ticiwch neu rhowch lythrennau blaen eich enw

1. Rwy'n cadarnhau fy mod wedi darllen a deall y daflen wybodaeth, dyddiedig 16.12.2015, Fersiwn 2 ar gyfer yr astudiaeth uchod. Rwyf wedi cael cyfle i ystyried y wybodaeth, a gofyn cwestiynau a chael atebion boddhaol iddynt. ☐
2. Rydw i'n deall bod fy mherson ifanc yn cymryd rhan yn wirfoddol a bod fy mherson ifanc yn rhydd i dynnu'n ôl unrhyw bryd, heb roi rheswm. ☐
3. Rwy'n rhoi caniatâd i wybodaeth bersonol fy mherson ifanc gael eu prosesu at y dibenion a eglurwyd imi. Deallaf y caiff gwybodaeth o'r fath ei thrin yn unol â thelerau Deddf Diogelu Data 1998. ☐
4. Rwy'n deall y gallai gwybodaeth fy mherson ifanc gael ei hadolygu gan unigolion cyfrifol o Fwrdd Iechyd Prifysgol Betsi Cadwaladr at ddibenion monitro ac archwilio. ☐

5. Deallaf y cedwir popeth yn gyfrinachol ac yn anhysbys ac na fydd posib adnabod fy mherson ifanc mewn unrhyw gyhoeddiad. ☐

6. Rwy'n deall efallai y bydd rhaid i'r ymchwilydd roi gwybod i aelodau'r Gwasanaeth Iechyd Meddwl Plant a'r Glasoed lleol mewn sefyllfaoedd lle gallai fy mherson ifanc neu eraill fod mewn perygl difrifol. ☐

7. Rwy'n cytuno y gall y tîm ymchwil ddefnyddio data dienw fy mherson ifanc ar gyfer ymchwil yn y dyfodol. (Mewn achosion felly, fel gyda'r project hwn, ni fyddai posib adnabod data mewn unrhyw adroddiad). ☐

8. Rwy'n deall y bydd y wybodaeth rwyf i wedi'i rhoi yn cael ei chyhoeddi fel adroddiad ac y byddaf yn derbyn copi. ☐

9. Rwy'n caniatáu i gyfweliadau fy mherson ifanc gael eu recordio ar dâp sain a fideo. ☐

10. Rwyf wedi rhoi gwybod i'r ymchwilydd am ymchwilion eraill mae fy mherson ifanc yn cymryd rhan ynddynt neu wedi cymryd rhan ynddynt dros y 12 mis diwethaf. ☐

Enw'r cyfranogwr	**Dyddiad**	**Llofnod**
Enw'r ymchwilydd	**Dyddiad**	**Llofnod**

GENERAL APPENDIX

APPENDIX 1

Circular Causality

The term circular causality was coined to express the interdependence of action in groups of people. Each person's action is seen as being influenced by others and influencing others simultaneously. Any action is therefore also a response, and a response is also an action. Thus, when working with families, finding out "who started it" is not productive as any sequence of events can be seen as dependant on previous interactions (Dallos & Draper, 2010). For example, when a parent and a teenager struggle with communicating, a linear explanation given by the parent might be that when the teenager withdraws, the parent feels incompetent and thus tries to engage the teenager, whilst the teenager might say that the parent is demanding, thus leading the teen to withdraw. From a circular perspective the parent's demanding behaviour is maintained by the teen's aloofness, and vice versa. The parent's behaviour and the teen's behaviour are both causing and caused by each other. In this sense, individuals are seen to influence each other in non-linear processes that create patterns of reciprocal interaction. The variables (i.e. people's behaviour) are seen as interdependent.

References

Dallos, R. & Draper, R. (2010). *An introduction to family therapy: systemic theory and practice* (3rd Ed.). McGraw Hill: Open University Press.

APPENDIX 2

Family Therapy and Process Research

Unlike psychodynamic or cognitive approaches which identified psychological problems as being within the individual's mind or cognitions, family therapy formulated individuals' problems as the result of unhelpful and inflexible relationship patterns within the individuals' immediate social context (usually the family). Families were seen to behave like systems. This means that members of the family influenced each other's behaviour, relationships between two or more family members could influence the whole family and patterns of behaviour and relationships could become entrenched. On the whole, individual problems were formulated as the result of the family's attempted solutions to difficulties raised by lifecycle transitions and socio-cultural factors.

Early family therapy approach focused on how power and authority was wielded in the family and how family rules were created and clarified (Minuchin, 1974). Later approaches began to see the family as a linguistic-system (Anderson & Goolishian, 1988). Their focus was on how family members communicated with one another, the stories they told about each other and how they made sense of what happened to them and to the identified patient. The therapist's stance in family therapy is one of curiosity, to gain an understanding of each family member's perspective and assist the family in developing more helpful ways of understanding their difficulties, ways that provide a solution to problematic behavioural patterns (Burnham, 1992). To do so the therapist needs to attend to all family members, identify unhelpful recursive patterns of communication in the family and disrupt them without losing the relationship with each family member.

The communication practices that the therapist and the family employ whilst interacting during a family therapy session are the target of process research. Process research

is concerned with questions regarding how therapy works, how alliance is maintained and how change actually occurs inside a therapy session (Dallos & Draper, 2010). Process research in psychotherapy initially focussed on coding therapist interventions and counting how often certain interventions occurred. This approach was generally unsuccessful and did not provide any new information (see Gale, 1991 for summary). Thus, researchers began using interactional sociolinguistics and other language-based approaches that allowed the tracking of moment-by-moment interactions between therapist and family members to uncover how the therapeutic conversation was jointly constructed (Gale, 1991; Peräkylä et al., 2008). These language-based approaches (including CA) offered analytical tools to describe clinically significant occurrences. This in turn could lead to an understanding as to how certain interactions may be related to change. Thus, language-based process research can inform theory development by exposing whether therapists act according to their theoretical model, and it can also inform outcome research by showing which processes in therapy can be linked to better outcomes.

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APPENDIX 3

Conversation Analysis, Discourse Analysis and Discursive Psychology: Navigating the Terminology

The literature on language-based process research is characterised by varied and disorientating terminology. The term "discourse analysis" in particular is often used broadly to describe any type of language-based approach (Antaki, 2008). This is potentially confusing as it suggests a common origin to profoundly different methodologies (Wooffitt, 2005; see Figure 1). In its broader understanding "discourse" refers to what people say or write. However, a subgroup of methodologies see "discourse" as meaning the social actions that are made visible through language. For example, a person saying "The window is open" could be performing the social action of "informing" another person, or of "requesting" that the situation be rectified and the window closed. In this sense spoken language is seen as performing social actions.

Conversation Analysis shares core features with other approaches, namely, discourse analysis, discursive psychology, narrative analysis, interactional sociolinguistics and critical and Foucauldian discourse analysis (Antaki, 2008):

1. Data must be "naturally occurring talk or text" as in, not produced in an experimental setting or invented;
2. Words must be understood within the immediate context of the unfolding talk or text;
3. Attention is given to the non-literal meaning of words;
4. The analyst reveals the social actions achieved by the structuring of talk or text in a specific manner.

These approaches differ in their underlying theory and methodology, which, together, specify what is to be considered "natural data", what is considered a "social action" and what counts as evidence for that action (Antaki, 2008).

Figure 1. Types of language-based methodologies based on Antaki (2008) and Wooffitt (2005). Overlapping circles indicate closely affiliated methodologies.

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APPENDIX 4

Transcription Sample [P5:451-511]

Th2: so that's like kind of erhm

Th2: pt that's where the domains are a bit unclear does that make sense

M: yeah ((M and YP nod))

Th2: because on your mum's mind is just is she safe is she safe yeah ((M and YP nod))

Th2: so 's that happen a lot is that one thing that

M: it's not as bad as what it was is it

YP: no

M: but if she if you do blow you blow in good style don't ya

((YP nods slowly)) ((YP and M exchange glances))

M: and it's hard to communicate isn't it if something's on your mind you don't you don't know how to approach me cause y- she thinks I'm gonna blow my stack whereas ninetynine percent of the time I'm calm but probably my expression will say otherwise because I panic so ye- your body language gives away

Th2: alright

M: (mine) till I keep calm

Th1: is that (i- is that) cause you might be worried

M: yeh

Th1: and I guess for any of us if we're worried sometimes our facial expression can look something else can't it really

M: yeah yeah

Th1: would tha- would you would you is your mum is your mum's face easy to read ((YP nods and smiles)) if if you know what I mean is that right

M: she she kno- she'd read me like a book by my expressions rather than the way I speak don't you

Th1: right okay okay

M: yeah

Th1: so so you you kinda can you help us understand that if that's alright whilst to say this whilst your mum is sitting there so what kind of expression does your mum have on her face that tell you things do you know if sh- would you be able to work out if she was ups- worried or or or

YP: hhhh yeah

Th1: is it is that a different look to when she's feeling a bit

YP: (w-) when mum's worried she goes quiet and like she doesn't talk about much hh hh and she ('s lots of) time on her phone and then when she like know something that I don't know she u- usually raises one eyebrow and like laughs hhh hhh ((YP laughs and looks at M who looks back and smiles))

Th1: hhhh

M: I don't know I'm doing it s-

YP: (and when mum) and when she's happy she's like this ((points at M))

Th1: right right

YP: hhh hhh hhh

Th2: (inaudible)

M: hhhe hhhe

Th2: what sort of stuff does make your mum raise one eyebrow ((laughing))

YP: I don't know ((laughing))

Th1: hhuhhu

M: I don't even know I'm doing it half the time ((laughing))

506 Th1: is it the same eyebrow

507 YP: yeah

508 Th1: is it

509 M: hhhehhhe ((laughter))

510 YP: hhh hhh ((laughter))

511 Th1: hh hh right hhhhh

APPENDIX 5

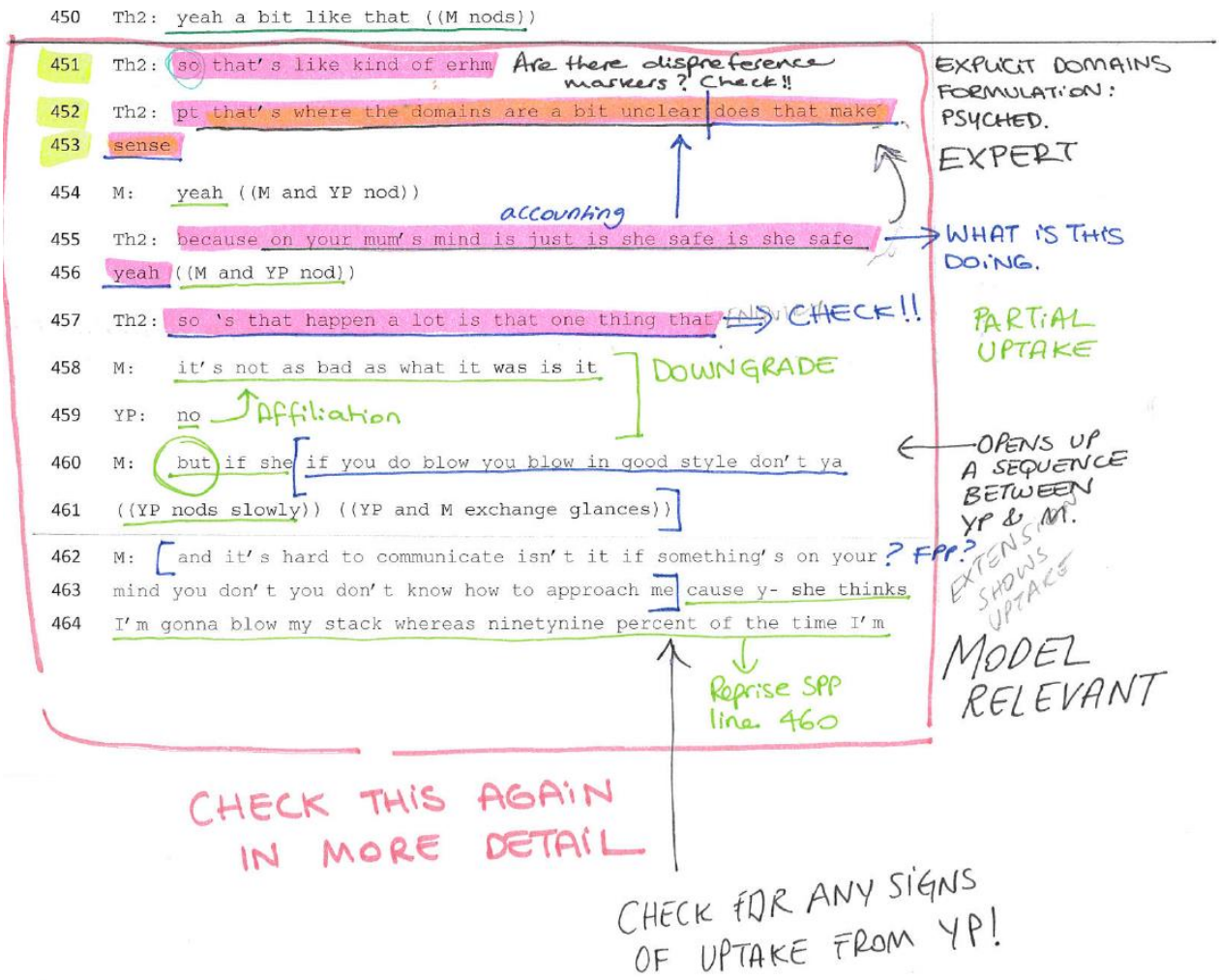
Annotated Transcription Sample [P5:451-511]

Key: Blue underlining: First Pair Part

Light green underlining: Second Pair Part

Dark green underlining: Sequence Closing Third or Expansion

Pink highlighting: Therapist intervention



465 calm but probably my expression will say otherwise because I panic
466 so ye- your body language gives away
467 Th2: alright → CHECK INTONATION ↗ SCT ↗ NEWS ↘ END?
468 M: (mine) till I keep calm
469 Th1: is that (i- is that) cause you might be worried → This is an action → leading to formulation
470 M: yeh
471 Th1: and I guess for any of us if we're worried sometimes our → FORMULATION DOMAIN IMPLICIT
472 facial expression can look something else can't it really
473 M: yeah yeah
474 Th1: would tha- would you would you is your mum is your mum's face
475 easy to read ((YP nods and smiles)) if if you know what I mean is
476 that right — PARTIAL UPTAKE — ENQUIRY — Cross Checking.
477 M: she she kno- she'd read me like a book by my expressions
478 rather than the way I speak don't you ANY SIGN OF UPTAKE??
479 Th1: right okay okay ACCEPTANCE
480 M: yeah — uptake of YP

Is this a new course of action? Is it still leading to a domain formulation? I'd almost call this DOMAINS ASSESSMENT

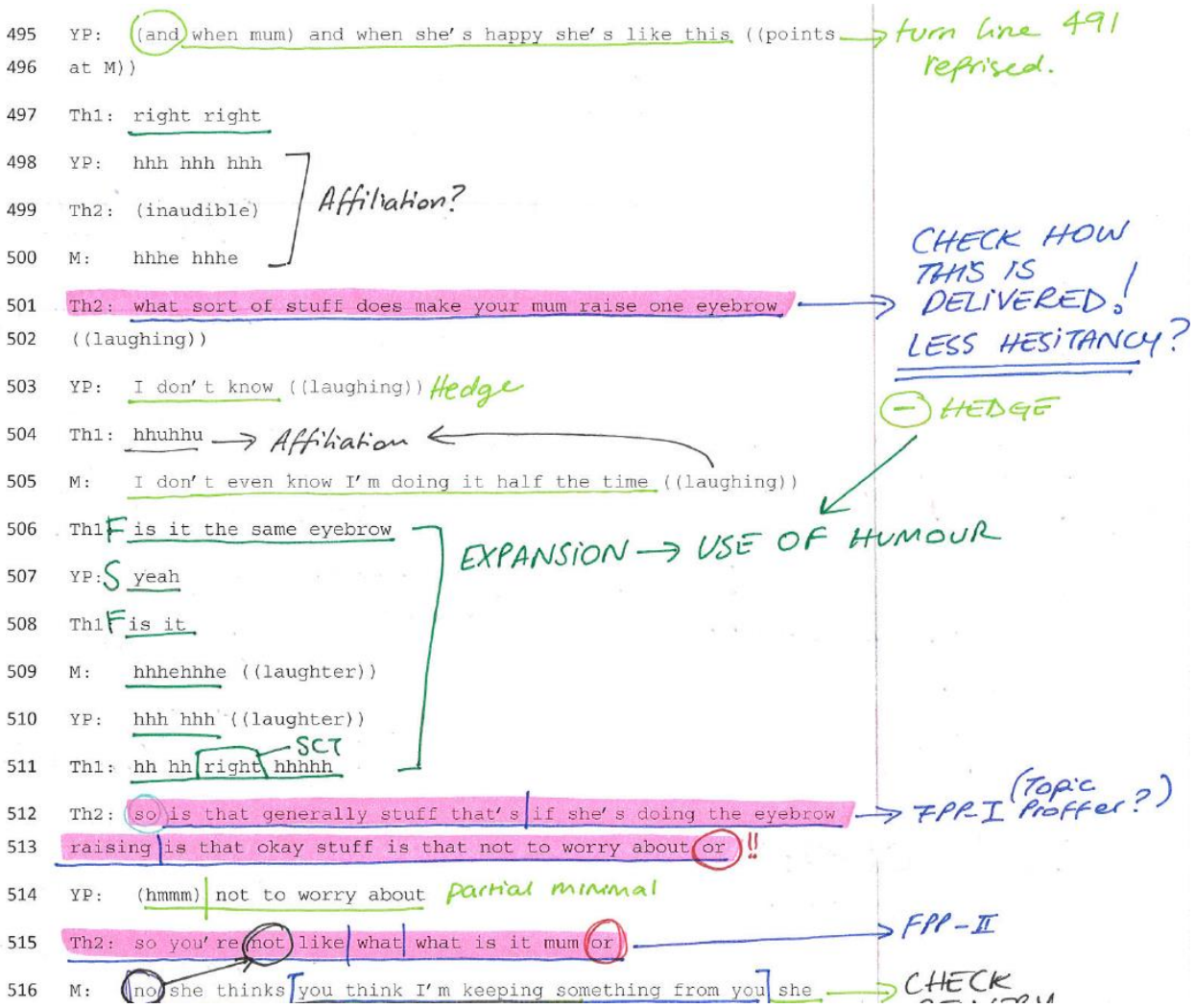
481 Th1: so so you you kinda can you help us understand that if that's → PREPRE
482 alright whilst to say this whilst your mum is sitting there so what
483 kind of expression does your mum have on her face that tell you
484 things do you know if sh- would you be able to work out if she was
485 ups- worried or or or

TOPIC PROFFER?1?

486 YP: hhhh yeah → AMBIVALENT: PARTIAL UPTAKE → ⊖ TOPIC PROFFER.
487 Th1: is it is that a different look to when she's feeling a bit → TOPIC PROFFER ?2? PURSUIT.

488 YP: (w-) when mum's worried she goes quiet and like she doesn't ⊕ TOPIC PROFFER
489 talk about much hh hh and she ('s lots of) time on her phone and
490 then when she like know something that I don't know she u- usually
491 raises one eyebrow and like laughs hhh hhh ((YP laughs and looks at
492 M who looks back and smiles))
493 Th1: hhhh → What's this?
494 M: I don't know I'm doing it s-

Protestation?


495 YP: (and when mum) and when she's happy she's like this ((points
496 at M))
turn line 491 reprised.
497 Th1: right right
498 YP: hhh hhh hhh
499 Th2: (inaudible)
Affiliation?
500 M: hhhe hhhe
501 Th2: what sort of stuff does make your mum raise one eyebrow
CHECK HOW THIS IS DELIVERED! LESS HESITANCY?
502 ((laughing))
503 YP: I don't know ((laughing)) Hedge
(-) HEDGE
504 Th1: hhuhhu → Affiliation
505 M: I don't even know I'm doing it half the time ((laughing))
506 Th1 F is it the same eyebrow
507 YP: S yeah
508 Th1 F is it
509 M: hhhehhhe ((laughter))
510 YP: hhh hhh ((laughter))
511 Th1: hh hh right hhhhh
SCT
EXPANSION → USE OF HUMOUR
512 Th2: so is that generally stuff that's if she's doing the eyebrow
FPP-I (Topic Proffer?)
513 raising is that okay stuff is that not to worry about or !!
514 YP: (hmmm) not to worry about
partial minimal
515 Th2: so you're not like what what is it mum or
FPP-II
516 M: no she thinks you think I'm keeping something from you she
CHECK

APPENDIX 6

Sequential Map of Transcription Sample [P5:451-511]

452 Formulation ? or Psyched ? /Technical: telling + understanding check

>> UPTAKE: token

455 Formulation/Technical: accounting for 452

>> UPTAKE: nods

457 Communication assessment: that happens a lot

>> PARTIAL UPTAKE: downgrade + understanding check YP + **MODEL CONSISTENT:** my expression says otherwise

469 Communication assessment: check worried? pre-psyched?

>> UPTAKE: token

471 Psyched/Non-Technical: I guess + if worried then facial expression unclear

>> UPTAKE: token

474 Communication assessment: M easy to read

>> UPTAKE: acknowledgement/telling

481 Communication assessment: Can YP work out if mum worried

>> UPTAKE: HEDGE: token

487 Communication assessment: reprise: Can YP work out if mum worried

>> UPTAKE: YP describes what M is like when worried

501 Communication assessment: what makes M raise eyebrow

>> **NO-UPTAKE:** YP HEDGES

Humour: expansion

>> YP and M laughter: affiliation

APPENDIX 7

Detailed Transcription of Psychoeducation Extracts [P5:452 & P5:471]

P5_452_15:29_Technical Terminology Paraphrase

T2: =yeah (.) a bit like that

(1.1)

T2: ⟶ so that's like kind of (.) e:rhm: (0.8) pt (0.3) that's where the domains are a bit unclear¿ (0.2) does that make sen[se¿]

M: [yeah]

(0.6)

T2: because on your mum's mind >°is just°< IS she safe is she safe (0.5) yeah¿

(3.0) ((M and YP nod))

T2: >so 's that happen a ↑lot< ↓is that one thing that¿

(0.5)

M: it's (.) not as (.) bad as (.) what it was (0.4) is it

(0.2)

P5-471_16:19_"if X then Y"

T1: is that (i- is that) (.) cause you: might be worried.

M: yeh

T1: →>and I guess< (0.2) for any of us if we're worried
sometimes ou:r [facial expression] [can look] =

M: ((nods)) [y:eah]

T1: = something else ca[n't it] really

M: ((nods))[y:eah]((nods))

(0.3)

T1: would tha- would you: (0.6) would you: (0.2) is your mum (.)
is your mum:'s face easy to read
((continues with communication assessment))

APPENDIX 8

Annotated Transcription of Psychoeducation Extract with Analysis of Function, Position and Features

Key: Light Blue: Prefaces

Dark Blue: Uncertainty markers

Pencil: Other features of interest

Light Blue dots: M nodding

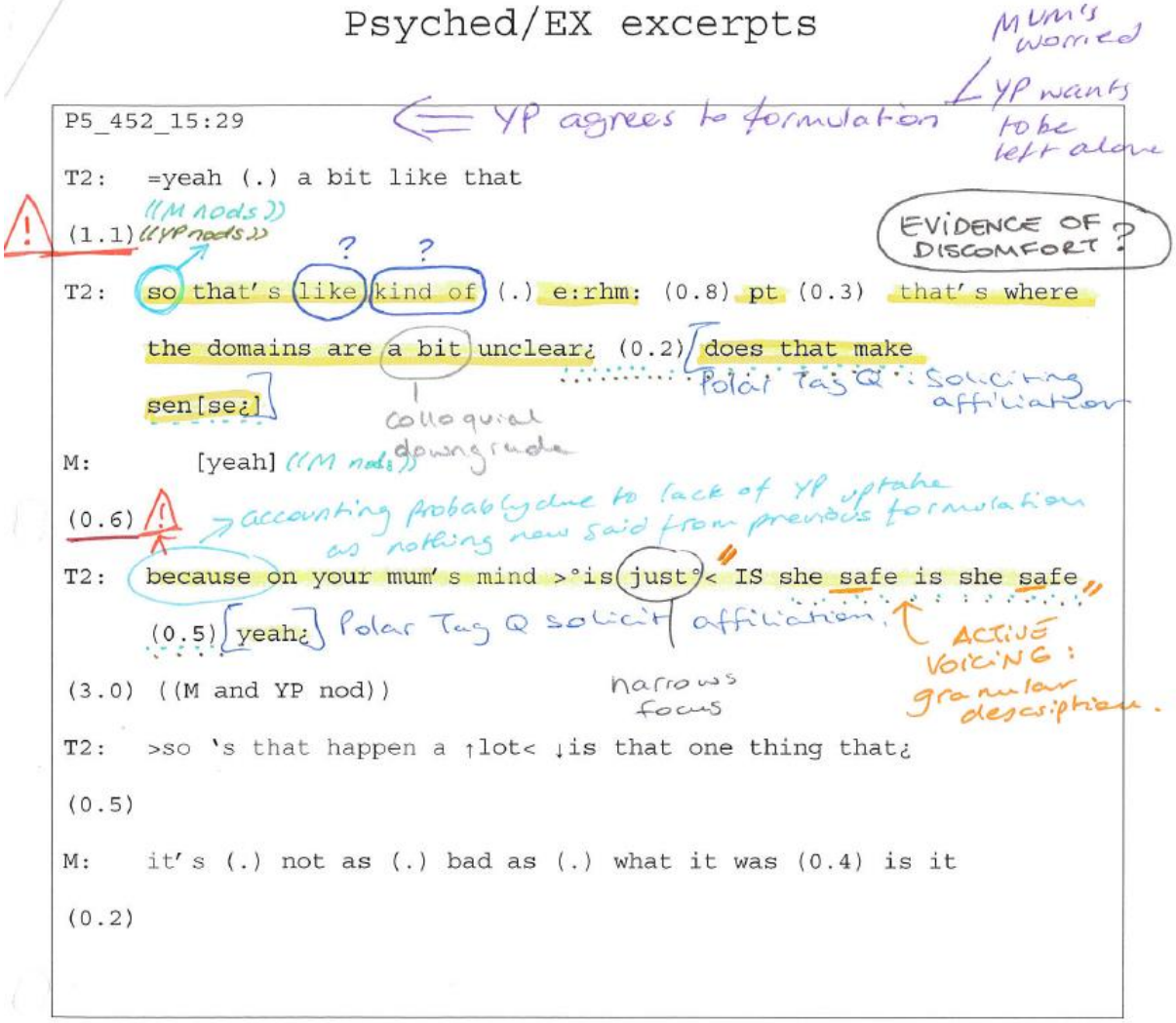
Puce dots: YP nodding

Orange: Reported speech

Blue ball point pen: Tag questions

Red: Potential sign of trouble – check video again for non-verbal signs of uptake

Psyched/EX excerpts



T2 comm an,
YP model relevant/want to be left alone
T2 formulation
YP Agreement yeah
T2 Psyched
M yeah agreement ~~YP nod~~
T2 Account
M& YP nod
T2 comm an.

P5:452-456	Post-expansion following YP agreeing on formulation Leads into communication assessment sequence	- Designed for: Delivering education - Uptake: minimal M "yeah" YP nods after elicitation	"so"-sequence initial: re-launching previous talk, on speaker's agenda, other-attentiveness **"like"?** **"kind of"?** "a bit" colloquial, downgrade of expert assertion? Polar tag question "does that make sense": solicit affiliation "because" offering account/colloquial paraphrase "just" narrowing? Active voicing: granular/concretizing Polar tag question: "yeah?" soliciting affiliation	*Technical paraphrase + incomplete colloquial paraphrase*

← COMM. AX WITH M'S MODEL RELEVANT EXAMPLE

P5-471_16:19

T1: is that (i- is that) (.) cause you: might be worried.
M: yeh
T1: >and I guess< (0.2) for any of us if we're worried sometimes ou:r facial expression [can look] something=
M: [y:eah]
T1: =else ca[n't it] really TAG Q.
M: [y:eah]
(0.3) ((M looks at YP))
T1: would tha- would you: (0.6) would you: (0.2) is your mum (.) is your mum:'s face easy to read... → COMM. AX. CONTINUES but NOT MODEL RELEVANT REPLY.

Non tech illustration example/ concretisation explicating evidence IF → THEN

M: "I panic" expren problem — Model relevant example

T1: comm anen - inquiry sequence of com inquiry — connect to emotional concern

M: agreement

T1: psyched → normalizing function

M: agreement

T1: pursues agreement with YP dropped → communication ax

P5:471	Post-expansion following M's agreement with communication assessment "she panics because she is worried"	- Designed for: delivering education and normalizing - Uptake: minimal "y:eah"	**"and" preface: connecting to prior talk?** "I guess": downgraded form of knowing/ evidential marker "any of us" "we" "our": affiliation "sometimes": vagueness? Polar-tag question: can't it?	*Non-technical illustration (exemplification/concretization) accounting, explicating evidence "if X then Y".*

APPENDIX 9

Examples of Non-Technical Scenarios and Formulation Format

Psychoeducation Sequences

Non-technical Scenarios

This format refers to use of scenarios and examples that do not rely on the technical terminology of the domains model. Non-technical scenarios (5 instances) were the most likely to go beyond the action of providing information, and were used for managing potential blame, mitigating potential disaffiliation and accounting for the therapy process. They were used most often in situations where the therapist's attempt at describing the therapy process had received minimal or no uptake from the family.

In extract 1 the mother (M) has just made a general statement (use of the unspecific "you") implying that parents can always tell when their child is distressed and that communication will be clear (lines 1-2).

Extract 1. [P6:726] Non-technical scenario

```
1   M:      as soon as you see anything on your child's face y
2           want to [know wha]t's wrong
3   T1:             [hm:     ]
4   (0.2)
5   T1:     hm
6   (0.5)
7   T1: ——→ .hh but- (0.2) but if- of course what can happen
8           sometimes,
9   (0.8)
10  T1:     through (.) not er not (.) inte[nded to happen]=
11  YP:                                    [((YP nods   ))]
12  T1:     .hh is (0.4) >sometimes a parent can say to a: you
13          person (1.2) w- w- what are you up to what's wrong
14  (0.2) ((M nods))
15  T1:     and it can be heard as (0.3) wh- why are you check
16          up on me
17  M:      hm: ((nodding))
```

The therapist (T1) initially receives M's statement with a minimal acknowledgement suggesting receipt but not agreement (lines 3 and 5; Stivers, 2008), then uses psychoeducation to introduce the idea that communication is not always clear, thus suggesting the concept of "domain mismatches". He does so by starting with a "but" preface (line 7), which immediately suggests that what is to come is in contrast to what M has said (Schegloff, 2007). The beginning of T1's turn-at-talk is laboured (inbreath, repetition and pause) suggesting the 'dispreferred' nature of this statement (Schegloff, 2007), dispreferred

in a conversation analytic sense, meaning that it does not align with M's previous statement. T1 seems to repair a statement as suggested by the cut-off on "if-" and the rush into the marker "of course" (line 7; Kitzinger, 2013), which as stated above indicates that self-evidence of the upcoming statement. This is followed by a passive form statement "what can happen sometimes", couched in tentativeness by the use of the modal verb "can" and the adverb "sometimes" (lines 7-8; Heritage, 2013). This statement also projects an upcoming storytelling. However, there is a lack of uptake or 'go-ahead' to the storytelling at this point, as manifested in a 0.8 second silence (line 9), suggesting potential interactional disaffiliation (Jefferson, 1989). Thus, T1 proceeds by inserting a laboured blame management statement (line 10), which through the emphasised use of the verb "intend" suggests that whatever is said reflects people's behaviour and not their true nature, thus meaning individuals are not to be held accountable for what T1 is about to say (McHoul & Rapley, 2003). This blame management formulation elicits some uptake from the young person (YP, line 11). T1 then resumes his storytelling (line 12), which uses membership category devices, and modal verb "can", as well as direct quotes to create a general yet vivid account of a potential scenario.

Formulation Format

This format refers to the use of technical domains terminology within a formulation (Antaki, 2008). These sequences (4) were more likely to be characterised by direct, non-tentative and prescriptive language. Its main action was to deliver psychoeducation. This format was always used after the family had provided an account of personal circumstances following a communication assessment, formulation or another psychoeducation sequence.

Extract 2 occurs after YP has given a detailed account of his interaction with a friend following an inquiry by T1. YP explains how initially he thought his friend was joking when he wrote that he wanted to die, then the young person realized his friend was serious. This

psychoeducation instance has the format of a formulation as it is repeating the young person's words but adding technical terminology to it.

Extract 2. [P6:595] Formulation format

```
1   T1: ⟶.hh so it started ↑off
2   YP:      um hmh=
3   T1: ⟶=clearly as an exploratory conversation with him
4   (0.6) ((M nods))
5   T1: ⟶>and then it got serious,
6   (0.2)
7   YP:      um hmh ((nodding))
8   (1.0)
9   T1: ⟶ so then you moved into a different domain didn't
10  (0.9)
11  T1: ⟶ °you moved into safety didn't ya,°
12  (2.3)
```

It is initiated with a "so" preface (line 1), that in this case refers to what YP has just said and therefore serves as a causal and impartial link between what YP has just said and what T1 is about to say (Antaki, 2008). Notably, this format of delivering psychoeducation is much more direct, T1 is stating the facts by making an assertion of the "it is X" type (Peräkylä, 2002), indicating the domain clarity of the interaction but also the self-evidential nature of the fact stated via the use of the adverb "clearly" followed by the technical term "exploratory conversation" (line 2) and by a polar tag question. Unlike other psychoeducation instances this one has a more instructional structure, which resembles the "known-answer questions" discussed above. And although there is some minimal uptake from M (line 4) there is none from YP. T1 then proceeds by repeating the YP's narrative (line 5), which

receives the YP's acknowledgment but nothing else (line 7). T1 then attempts the same type of psychoeducation format twice, with a negatively formatted polar tag question, which could be seen as an upgraded attempt at gaining alignment (Stivers, 2010; line 9 and 11). Both attempts receive no uptake from either M or YP. The sequence continues with M adding information to YP's previous account therefore almost sequentially deleting T1's intervention, in the sense that she continues as if this psychoeducational intervention had not occurred.

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Word Count Statement

Thesis Component	**Word Count**
Thesis Abstract	188
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Empirical Paper	6,000
Contributions to Theory and Clinical Practice	4,764

Word count excluding tables, figures and reference lists	
Thesis Abstract	188
Literature Review	3,022
Empirical Paper	4,754
Contributions to Theory and Clinical Practice	4,088
Total	**12,052**

Appendices including figures, tables and reference lists, excluding author guidelines, ethics section and ethics appendices	
Total	**8,242**

Total Word Count	**20,294**