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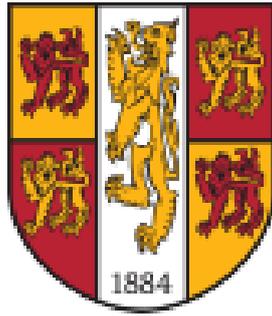
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Sleep-wake reversal among people with psychosis: A
functional contextualist interpretation

Stuart William Ivory

North Wales Clinical Psychology Programme

January 2024

Submitted in partial fulfilment of the requirements for the degree of
Doctor of Clinical Psychology

I hereby declare that this thesis is the results of my own investigations, except where otherwise stated. All other sources are acknowledged by bibliographic references. This work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree unless, as agreed by the University, for approved dual awards.

- Yr wyf drwy hyn yn datgan mai canlyniad fy ymchwil fy hun yw'r thesis hwn, ac eithrio lle nodir yn wahanol. Caiff ffynonellau eraill eu cydnabod gan droednodiadau yn rhoi cyfeiriadau eglur. Nid yw sylwedd y gwaith hwn wedi cael ei dderbyn o'r blaen ar gyfer unrhyw radd, ac nid yw'n cael ei gyflwyno ar yr un pryd mewn ymgeisiaeth am unrhyw radd oni bai ei fod, fel y cytunwyd gan y Brifysgol, am gymwysterau deuol cymeradwy. Stuart Ivory, 9.1.24

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Thesis abstract

This thesis includes an empirical study considering sleep-wake reversal and psychosis from a Functional Contextualist perspective and a systematic review of the literature regarding moderators of rule-based insensitivity, a theoretical principle associated with psychological suffering within Relational Frame Theory. While the systematic review seeks to explore the principles underpinning functional contextual theories of psychological suffering, the empirical paper seeks to apply these principles to the exploration and description of sleep behaviours and psychosis. The thesis concludes with a discussion of implications for future research and practice.

Relational Frame Theory argues that rule-based insensitivity to changes in environmental contingencies underlies human suffering. Empirical links between theory and research serve as an important quality measure for evidence based psychological therapies. A systematic review was therefore conducted to explore the factors that moderate rule-based insensitivity. Preliminary evidence was found to suggest that rule based insensitivity may be increased when (a) where rules specify a socially mediated rather than environmentally mediated consequence and (b) where there is a longer history of deriving a rule from other stimulus relations. It is possible that more complex relations exist between rule based insensitivity and relational coherence and psychological suffering. Confidence in findings was generally low and a need for further research was identified.

consistent with past reinforced verbal behaviours

A qualitative empirical study is reported in which participant experiences of sleep are interpreted within a Functional Contextualist perspective. Participants discussed contextual factors and intended behavioural functions that were associated with sleep-wake reversal. Lack of meaningful occupation and activities was highlighted as a potentially important factor underlying the maintenance of sleep-wake reversal in the context of psychosis. Sleep-

wake reversal was further discussed in terms of experiential avoidance of aversive daytime and night-time experiences.

Moderators of the Rule Based Insensitivity Effect: A Systematic Review

Stuart Ivory (North Wales Clinical Psychology Programme), Robin Owen (Betsi Cadwaladr University Health Board), Mike Jackson (North Wales Clinical Psychology Programme)

Corresponding author: Stuart Ivory, stuart.ivory@nhs.net

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Abstract

Background. Psychological suffering has been argued to be the result of adherence to rules that reduce a person's ability to respond effectively to their environment. This conceptualisation of psychological suffering has important theoretical implications within Relational Frame Theory and Acceptance and Commitment Therapy. This review sought to systematically examine the evidence for factors that might moderate this effect among adults.

Methodology. A systematic literature search was conducted following PRISMA guidelines of MEDLINE, PsycINFO and PsycARTICLES databases. Seven hundred and ninety-three records were screened and 22 records, reporting 29 experimental studies, were deemed eligible for inclusion. These studies were examined to determine if they provided evidence for the existence of variables that moderated rule-based insensitivity to changes in direct contingencies. Narrative synthesis of findings was guided by assessments of the quality of evidence available for any potential moderating variables.

Results. Limited evidence emerged to support the existence of variables that moderate the rule based insensitivity effect. Preliminary evidence was found to suggest that relational coherence, relational derivation and type of rule may moderate rule-based insensitivity, however confidence in these findings was low. Results showed that after a contingency change lower levels of derivation and socially, as opposed to environmentally, mediated consequences were associated with higher rates of rule-based insensitivity. The direction of effect for coherence varied depending on how rule-based insensitivity was measured.

Preliminary evidence emerged to suggest that the relationship between psychological suffering and rule-based insensitivity may vary depending on clinical presentation. However, confidence in this finding was very low. Theoretical implications and suggestions for future research are discussed.

Conclusion. Despite the importance of rule-based insensitivity with Relational Frame

Theory, there has been limited empirical exploration of factors that may influence this effect.

Further high-quality research is needed to bridge the gap between theoretical treatments of rule based insensitivity and applied practice.

Introduction

Operant learning is a fundamental tenet of behavioural accounts of human behaviour, whereby behaviour can be analysed in terms of antecedent conditions, responses and consequences. The consequences following a response influence the likelihood of the behaviour being repeated under similar conditions (Törneke et al., 2008). However, this does not explain how humans are able to respond appropriately and with complexity to novel stimuli in the absence of any history of shaping contingencies.

Skinner (1966) introduced the concept of “rule-governed behaviour” (RGB) to try to explain complex human behaviour, positing that verbal antecedents can act as rules and influence responses without the need for previous contact with shaping contingencies. RGB can take a number of forms, provided that a rule implicitly or explicitly states a behaviour and a consequence. “Pliance” refers to RGB which is under the control of consequences mediated by the speaker of the rule. This is typically the earliest form of RGB learned and is regarded as the least effective in guiding adult behaviour. “Tracking” refers to RGB in which the rule is reinforced by its correspondence with direct contingencies in the environment. A third form of rule governed behaviour is augmenting which alters the extent to which stimuli function as consequences (Hayes et al., 2001, 2012; Törneke, 2010). With the development of Relational Frame Theory (RFT) came hypotheses about the process by which verbal rules can modify stimulus functions and influence responding in the absence of prior shaping contingencies (Hayes et al., 2001; Törneke et al., 2008), namely Arbitrarily Applicable Relational Responding (AARR). AARR is a process whereby unreinforced behaviour can arise from derived verbal relationships between previously reinforced responses within a

“relational frame” (Hayes et al., 2001; Törneke, 2010). This provides a theoretical framework for the exploration of how external and internal verbal stimuli influence human behaviour.

While RGB confers many benefits, rules may continue to exert control over behaviour even after changed contingencies render the rule inaccurate (Dixon et al., 2000; Hayes et al., 1986; Kissi et al., 2020; McAuliffe et al., 2014). This has led to conceptualisations of psychological suffering as the adherence to rules that impede effective adaptation to environmental demands and consequences (Blackledge & Drake, 2013). For example, if persecutory delusions are considered as a form of derived rule-based behaviour (O’Donoghue et al., 2018; Stewart et al., 2016) then reduced sensitivity to negative social, emotional and behavioural consequences may help explain their persistence. RBI has been found to correlate with psychological rigidity (Wulfert et al., 1994) which is argued to be central to psychological suffering (Harris, 2019; Hayes et al., 2012). Similarly, use of tracking and augmenting have been found to have stronger associations with psychological wellbeing than pliance (Sheldon et al., 2004), which is thought to be most strongly related to RBI (Hayes et al., 2001, 2012). Research into specific manifestations of psychological suffering has suggested that high levels of rule-governance may be associated with depression in adolescents (McAuliffe et al., 2014) and delusions in adult inpatients (Monestès et al., 2014), lending preliminary empirical support to the transdiagnostic nature of this process.

Within clinical applications of RFT, the most prominent of which being Acceptance and Commitment Therapy (ACT), influencing RGB is a core process. RBI and excessive reliance on pliance and tracking are seen as problematic processes to be undermined, while augmenting is emphasised in order to increase the influence of delayed consequences (Hayes et al., 2012). Empirical support for underpinning theory has been suggested as a key quality measure for evidence-based psychological therapies (David & Montgomery, 2011) yet empirical support for the relationship between tracking, pliance, augmenting and RBI is

surprisingly limited (Kissi et al., 2017). More broadly, there is support for the existence of a rule-based insensitivity effect, with a recent systematic review finding a large, albeit preliminary, effect of verbal rules on insensitivity to contingencies (Cohen's $d=.76$; Kissi et al., 2020). However, only one study was identified which explored RBI in relation to psychological suffering. This may have been due to exclusion of smaller studies, which are common in the investigation of operant behaviour given the time-consuming nature of establishing novel responses (Skinner, 1958). Overall, Kissi et al.'s (2020) findings were deemed preliminary and a need was identified for exploration of factors that moderate RBI.

To the best of our knowledge, despite the theoretical and clinical implications of RBI, the literature on potential moderators of the effect has not been systematically investigated. As such, this review sought to systematically review the literature regarding potential factors which moderate the rule-based insensitivity effect.

Method

Protocol

A review protocol was finalised on 16th October 2022 using the PRISMA statement and PRISMA Protocol Checklist (Page et al., 2021). A minor amendment was made on 13th January 2023 to specify that if a screened abstract was deemed ambiguous the full text would be reviewed against inclusion and exclusion criteria.

Criteria for considering studies for this review

Peer reviewed experimental studies which investigated potential moderating factors of the RBIE among adults were considered for inclusion in this review.

Specifically, studies were required to ask adult participants to follow self- or externally- generated rules that were initially accurate and became inaccurate after a change in contingencies. Studies were also required to manipulate a potential moderating variable

across experimental conditions and measure its influence on sensitivity to contingency changes. No further restrictions were placed on how RGB was measured given heterogeneity in the operationalisation of RBIE in the existing literature (Kissi et al., 2020). Studies had to be available in English language to be eligible for inclusion.

Search methods for identification of studies

An electronic search was conducted of PsycINFO, PsycARTICLES and MEDLINE databases. A search strategy was adapted from Kissi et al. (2020), with advice from an academic support librarian, to include terms that might indicate an investigation of moderating factors. Terms were also included for a number of psychological difficulties or psychiatric diagnoses given theoretical links between the RBIE and psychological suffering. No date limits were set for the search.

Including descriptors of specific tasks (e.g. “match to sample” and “conditional discrimination”) that are commonly used in rule-based insensitivity research was trialled. This did not contribute to additional records being identified so these terms were not included in the final search strategy. Extending the search strategy to include specific psychometric tests such as the Wisconsin Card Sort Test and the Iowa Gambling Task – Contingency Shifting Variant was also considered and trialled. Although these tests feature unsignalled changes in contingencies, participants do not begin the task with an accurate verbal rule and responding is shaped by the contingencies present in the task. As such these procedures did not meet the criteria for inclusion in this review.

The final search strategy was (“rule governed behavior” OR “rule-governed behavior” OR “RGB” OR “rule governed insensitivity” OR “rule-governed insensitivity” OR “rule-based insensitivity” OR “rule based insensitivity” OR “rule based behaviour” OR “rule-based behaviour” OR “rule based behavior” OR “rule-based behavior” OR “verbal regulation” OR “instructional control” OR “verbal rule” OR “instructed behavior” OR “instructed behaviour”

OR "instructed learning" OR "instruction following" OR "instruction-following" OR "rule following" OR "rule-following") AND (effects OR effect OR moderat* OR influenc* OR correlation OR "mental health" OR depression OR anxiety OR psychosis OR delusions OR hallucinations OR schizophrenia OR distress OR "psychological problems").

Data collection and analysis

After removal of duplicates, titles and abstracts were screened against the inclusion and exclusion criteria by the first author. Full text records were then screened against inclusion and exclusion criteria by the first author. A random selection of abstracts and full texts were screened by the third author to assess the reliability of screening. Any disagreements regarding screening decisions were discussed within the research team and a decision reached by consensus.

Data was extracted from included records by SI using a form piloted on a random subset of records. Study and source characteristics extracted were: year of publication, the country in which the first author worked at the time of publication, study design (quasi experimental design or Randomised Controlled Trial), the type of task, procedure and analysis used to examine the RBIE, the characteristics of potential moderating variables examined, whether a moderating effect was found and the significance, and the direction and size of any effects found. Additional task characteristics were extracted for reinforcement schedules, nature of consequences, and the nature of the responses required from participants. Sample characteristics extracted were size of sample, mean or range of age of sample, gender ratio of sample, and the sampling method used.

Reinforcement schedule data was transformed to be categorised as either variable, fixed interval, variable ratio, fixed ratio, intermittent or multiple schedule to allow comparison across studies. Responses required from participants were categorised as being either a discrete simple response, a discrete choice response or a complex response.

Following data extraction, a narrative synthesis was performed with findings tabulated and comparisons between studies described. Heterogeneity in effect directions indicated against conducting a meta-analysis (Deeks et al., 2019) , and combining p values or estimates of effect was precluded by variation in outcome measures (McKenzie & Brennan, 2022). Vote counting was also deemed inappropriate since both an increase or decrease in RGB indicates a potential moderating effect of a variable, meaning that creating a binary variable for positive and negative findings was not possible.

Assessment of risk of bias in included studies

Due to the inclusion of different study designs, design-specific critical appraisal tools developed by the Joanna Briggs Institute were used to inform quality assessment. GRADE criteria was used to categorise confidence in overall and study level findings as High, Moderate, Low or Very Low (Atkins et al., 2004). Quality assessments can be found in tables 1 and 2.

Table 1*Quality Assessments for Randomised Trials*

| Study citation | Study # | Checklist Item | | | | | | | | | | | | | Quality |
|-----------------------------|---------|----------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|---------|
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | |
| Baruch et al. (2007) | 1 | ? | ? | Yes | Yes | No | No | Yes | N/A | No | Yes | Yes | Yes | Yes | Low |
| Bern et al. (2021) | 2 | ? | ? | Yes | Yes | ? | ? | Yes | N/A | No | Yes | Yes | Yes | Yes | Low |
| Dixon & Hayes (1998) | 4 | ? | ? | ? | Yes | No | Yes | Yes | N/A | Yes | Yes | Yes | ? | Yes | V. Low |
| deGrandpre & Buskist (1991) | 3 | ? | ? | ? | Yes | No | ? | Yes | N/A | Yes | Yes | No | No | Yes | V. Low |
| Harte et al. (2017) | 9, 10 | ? | ? | Yes | Yes | ? | ? | Yes | N/A | No | Yes | Yes | Yes | Yes | Low |
| Harte et al. (2018) | 11, 12 | ? | ? | Yes | Yes | ? | No | Yes | N/A | No | Yes | Yes | Yes | Yes | Low |
| Harte et al. (2020) | 13, 14 | No | No | Yes | Yes | No | ? | Yes | N/A | No | Yes | Yes | Yes | Yes | Low |
| Harte et al. (2021) | 15, 16 | ? | ? | Yes | Yes | No | ? | Yes | N/A | No | Yes | Yes | Yes | Yes | Low |
| Henley et al. (2017) | 17 | ? | ? | Yes | Yes | No | ? | No | N/A | Yes | Yes | Yes | No | Yes | V. Low |
| Joyce & Chase (1990) | 18 | ? | ? | Yes | Yes | ? | ? | Yes | N/A | Yes | Yes | Yes | No | Yes | V. Low |
| Kissi et al. (2018) | 19 | Yes | Yes | Yes | Yes | No | ? | Yes | N/A | No | Yes | Yes | Yes | Yes | Mod |
| Kissi et al. (2021) | 20-22 | Yes | ? | Yes | Yes | No | ? | Yes | N/A | No | Yes | Yes | Yes | Yes | Mod |
| Newman et al. (1994) | 26 | ? | ? | N/A | Yes | Yes | ? | Yes | N/A | Yes | Yes | Yes | No | Yes | V. Low |
| Newman et al. (1995) | 27 | ? | ? | N/A | Yes | ? | ? | No | N/A | Yes | Yes | Yes | No | Yes | V. Low |

Table 2*Quality Assessments for Quasi-Experimental Trials*

| Study citation | Study # | Checklist Item | | | | | | | | | Quality |
|-------------------------------|---------|----------------|-----|-----|-----|-----|-----|-----|-----|-----|---------|
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | |
| Donadelli & Strapasson (2015) | 5, 6 | Yes | N/A | N/A | No | Yes | N/A | Yes | Yes | No | V. Low |
| Fox & Pietras (2013) | 7 | Yes | Yes | Yes | No | Yes | N/A | Yes | Yes | No | V. Low |
| Haas & Hayes (2006) | 8 | Yes | ? | N/A | Yes | No | N/A | Yes | Yes | Yes | Low |
| Miler et al. (2014) | 23 | Yes | ? | N/A | Yes | No | N/A | Yes | Yes | No | V. Low |
| Monestes et al. (2014) | 24 | No | No | No | Yes | No | N/A | Yes | Yes | No | V. Low |
| Nergaard & Couto (2021) | 25 | Yes | Yes | N/A | Yes | Yes | N/A | Yes | Yes | No | V. Low |
| Rosenfarb et al. (1993) | 28 | No | Yes | ? | Yes | Yes | N/A | Yes | Yes | Yes | Low |
| Wulfert et al. (1994) | 29 | No | ? | Yes | Yes | Yes | N/A | Yes | Yes | No | V. Low |

Results

Results of database searches

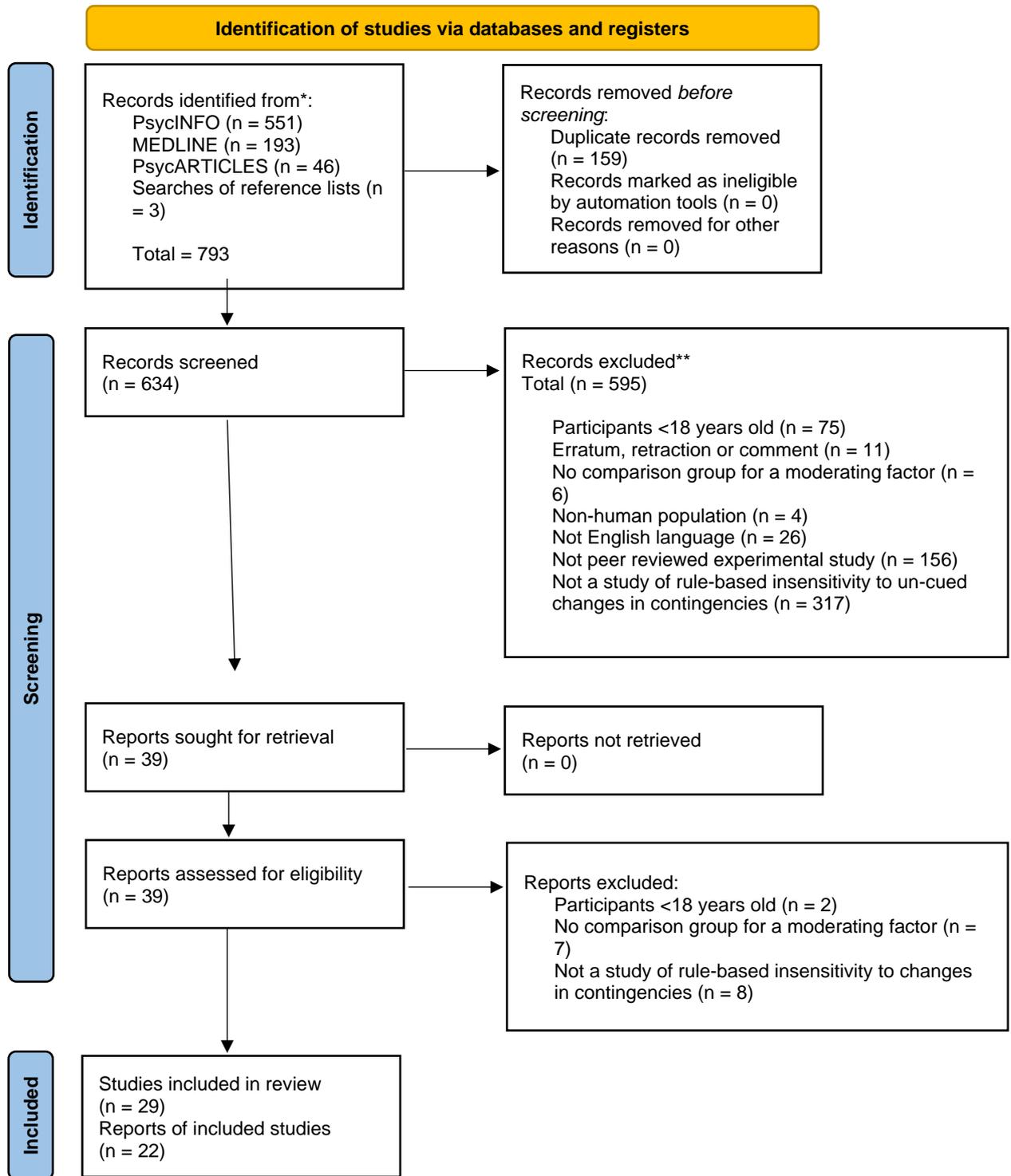
Searches were conducted on 4th November 2022 by the first author and repeated on 4th January 2023. Database searches generated 790 records. A further three records that met inclusion criteria were identified from reference lists of screened studies resulting in a final set of 793 records to be assessed for eligibility.

After removal of duplicates, 633 titles and abstracts were screened against the inclusion and exclusion criteria. Thirty-nine full text records were retained for screened against inclusion and exclusion criteria. Forty abstracts and ten full text records were screened by the third author to assess the reliability of screening. Cohen's Kappa for initial ratings was 0.75 indicating substantial agreement and full consensus was reached after discussion. A final total of 22 records, reporting 29 eligible studies, were retained for data extraction and synthesis. Figure 1 documents the stages of inclusion and exclusion of records.

Overview of study design and demographic information

The search yielded 22 records eligible for inclusion in this review, reporting 29 separate studies on moderating effects of RBIE. The 22 included records were published between 1979 and 2021, with the majority being published in either the 1990s (n=7) or 2010s (n=8). Of the 29 studies (n=1454), 18 reported using some form of randomisation to allocate participants to conditions, with the remaining 12 being classified as quasi-experimental designs.

Figure 1
Prisma Flowchart of Study Identification Process



Studies were conducted in the USA (n=11), Belgium (n=12), Brazil (n=2), Norway (n=1), Sweden (n=1), Réunion (n=1), and Canada (n=1). All studies used convenience sampling, with three of these then using additional screening criteria to generate a purposive sample (Baruch et al., 2007; Rosenfarb et al., 1993; Wulfert et al., 1994). Only one study did not recruit solely from a university or college population (Monestès et al., 2014) and recruited from a psychiatric inpatient population, while recruiting a comparison group from a college population. Sample sizes ranged from 6-216 (Median = 45).

All studies used laboratory-based tasks to try to elicit a RBIE. The studies either involved match-to-sample tasks or tasks in which points were gained by pressing buttons in accordance with a specified or unspecified reinforcement schedule. Outcome measures of RBIE included number of points earned, number or percentage of schedule consistent responses, number of responses after a contingency change before contingency sensitive responding occurred, reversion back to rule reliance after contacting contingencies, and the “switch points” (the point in a progressive multiple schedule at which a switch in responding occurs in response to increasing latency between reinforcement delivery.)

There was variance between studies in how rule-based responding was operationalised; some studies defined it as any instance of rule-consistent responding, while some considered whether overall patterns of responding were more consistent with rules as opposed to contingencies. Furthermore, some studies considered all responses after a contingency change in their analysis while others restricted analysis to later responses to control for variability in responding while participants adapted to a contingency change. A number of studies required participants to show a stable pattern of responding over a number of trials before they were exposed to a contingency change, with some studies excluding participants who did not show a stable pattern of correct responding and some exposing them to additional training trials until they did. Extracted study characteristics can be found in

tables 3-5.

Table 3
Sample Characteristics and Study Design

| Citation | Study number | N | Age (mean or range) | gender ratio (F:M:O) | Study design | Sampling method |
|-------------------------------------|--------------|-----|---------------------|----------------------|--------------------|-----------------|
| Baruche et al. (2007) | 1 | 29 | 20.6 | 18:11 | Quasi-experimental | Purposive |
| Bern et al. (2021) | 2 | 216 | 23.5 | 138:70:3 | Randomised | Convenience |
| deGrandpre and Buskist (1991) | 3 | 16 | >18 | 7:9 | Randomised | Convenience |
| Dixon and Hayes (1998) | 4 | 25 | >18 | 14:11 | Randomised | Convenience |
| Donadelli & Strapasson (2015) exp 1 | 5 | 8 | 20.8 | - | Quasi-experimental | Convenience |
| Donadelli & Strapasson (2015) exp 3 | 6 | 8 | 18.8 | - | Quasi-experimental | Convenience |
| Fox and Pietras (2013) | 7 | 7 | 19-23 | 3:4 | Quasi-experimental | Convenience |
| Haas and Hayes (2006) | 8 | 60 | >18 | - | Quasi-experimental | Convenience |
| Harte et al. (2017) exp 1 | 9 | 67 | 22.67 | 49:18 | Randomised | Convenience |
| Harte et al. (2017) exp 2 | 10 | 140 | 22.04 | 106:34 | Randomised | Convenience |
| Harte et al. (2018) exp 1 | 11 | 88 | 22.36 | 62:26 | Randomised | Convenience |
| Harte et al. (2018) exp 2 | 12 | 98 | 22.27 | 75:23 | Randomised | Convenience |
| Harte et al. (2020) exp 1 | 13 | 60 | 20 | 74:24 | Quasi-experimental | Convenience |
| Harte et al. (2020) exp 2 | 14 | 90 | 20.39 | 95:20 | Quasi-experimental | Convenience |
| Harte et al. (2021) Exp 1 | 15 | 67 | 21.63 | 44:23 | Randomised | Convenience |
| Harte et al. (2021) Exp 2 | 16 | 72 | 20.52 | 26:46 | Randomised | Convenience |
| Henley et al. (2017) | 17 | 16 | 20.3 | 15:1 | Randomised | Convenience |
| Joyce and Chase (1990) exp 1 | 18 | 19 | 18-24 | 9:7 | Randomised | Convenience |
| Kissi et al. (2018) | 19 | 45 | 24 | 37:8 | Randomised | Convenience |
| Kissi et al. (2021) exp 1 | 20 | 60 | 23 | 49:11 | Randomised | Convenience |
| Kissi et al. (2021) exp 2 | 21 | 60 | 20 | 46:14 | Randomised | Convenience |
| Kissi et al. (2021) exp 3 | 22 | 57 | 22 | 43:14 | Randomised | Convenience |
| Miller et al. (2014) | 23 | 6 | 19.86 | 5:1 | Quasi-experimental | Convenience |
| Monestes et al. (2014) | 24 | 47 | 30.2 | 26:21 | Quasi-experimental | Purposive |

| Citation | Study number | N | Age (mean or range) | gender ratio (F:M:O) | Study design | Sampling method |
|-------------------------|---------------------|----------|----------------------------|-----------------------------|---------------------|------------------------|
| Nergaard & Couto (2021) | 25 | 9 | 20-24 | 5:4 | Quasi-experimental | Convenience |
| Newman et al. (1994) | 26 | 18 | >18 | - | Randomised | Convenience |
| Newman et al. (1995) | 27 | 18 | >18 | - | Randomised | Convenience |
| Rosenfarb et al. (1993) | 28 | 24 | >18 | 24:0 | Quasi-experimental | Purposive |
| Wulfert et al. (1994) | 29 | 24 | >18 | 15:11 | Quasi-experimental | Purposive |

Table 4
Study Characteristics

| Citation | Study number | Type of task | Procedure | Type of analysis | Control condition for RBIE | Reinforcement schedule | Nature of responses from participants | Nature of consequences |
|-------------------------------------|---------------------|---|--|---------------------------------------|-----------------------------------|-------------------------------|--|-------------------------------------|
| Baruche et al. (2007) | 1 | Conditional discrimination task | Unsignalled contingency change | Between groups performance comparison | No | Continuous | Discrete choice responses | Points |
| Bern et al. (2021) | 2 | Conditional discrimination task | Unsignalled contingency change | Between groups performance comparison | Yes | Intermittent | Discrete choice responses | Points |
| deGrandpre and Buskist (1991) | 3 | Conditional discrimination task | Unsignalled change in instruction accuracy | Between groups performance comparison | No | Intermittent | Discrete simple responses | Points |
| Dixon and Hayes (1998) | 4 | Reinforcement dependent on pattern of key presses | Unsignalled contingency change | Between groups performance comparison | Yes | Continuous | Discrete simple responses | Points and positive verbal feedback |
| Donadelli & Strapasson (2015) exp 1 | 5 | Conditional discrimination task | Unsignalled change in instruction accuracy and contingency | Within group performance comparison | No | Continuous | Discrete choice responses | Points exchangeable for money |

| Citation | Study number | Type of task | Procedure | Type of analysis | Control condition for RBIE | Reinforcement schedule | Nature of responses from participants | Nature of consequences |
|-------------------------------------|--------------|--|--|---------------------------------------|----------------------------|---|---------------------------------------|-------------------------------|
| Donadelli & Strapasson (2015) exp 3 | 6 | Conditional discrimination task | Unsignalled change in instruction accuracy and contingency | Within group performance comparison | No | Continuous | Discrete choice responses | Points exchangeable for money |
| Fox and Pietras (2013) | 7 | Task in which average reinforcement interval could be minimised depending on responses | Unsignalled contingency change | Within group performance comparison | No | Fixed interval and progressive interval | Discrete simple responses | Monetary reward |
| Haas and Hayes (2006) | 8 | Conditional discrimination task | Unsignalled contingency change | Between groups performance comparison | Yes | Multiple schedules | Discrete simple responses | Points |
| Harte et al. (2017) exp 1 | 9 | Conditional discrimination task | Unsignalled contingency change | Between groups performance comparison | No | Continuous | Discrete choice responses | Points |
| Harte et al. (2017) exp 2 | 10 | Conditional discrimination task | Unsignalled contingency change | Between groups performance comparison | Yes | Continuous | Discrete choice responses | Points |
| Harte et al. (2018) exp 1 | 11 | Conditional discrimination task | Unsignalled contingency change | Between groups performance comparison | No | Continuous | Discrete choice responses | Points |

| Citation | Study number | Type of task | Procedure | Type of analysis | Control condition for RBIE | Reinforcement schedule | Nature of responses from participants | Nature of consequences |
|---------------------------|---------------------|--|--------------------------------|---------------------------------------|-----------------------------------|---|--|-------------------------------|
| Harte et al. (2018) exp 2 | 12 | Conditional discrimination task | Unsignalled contingency change | Between groups performance comparison | No | Continuous | Discrete choice responses | Points |
| Harte et al. (2020) exp 1 | 13 | Conditional discrimination task | Unsignalled contingency change | Between groups performance comparison | No | Continuous | Discrete choice responses | Points |
| Harte et al. (2020) exp 2 | 14 | Conditional discrimination task | Unsignalled contingency change | Between groups performance comparison | No | Continuous | Discrete choice responses | Points |
| Harte et al. (2021) Exp 1 | 15 | Conditional discrimination task | Unsignalled contingency change | Between groups performance comparison | No | Continuous | Discrete choice responses | Points |
| Harte et al. (2021) Exp 2 | 16 | Conditional discrimination task | Unsignalled contingency change | Between groups performance comparison | No | Continuous | Discrete choice responses | Points |
| Henley et al. (2017) | 17 | Task in which average reinforcement interval could be minimised depending on responses | Unsignalled contingency change | Between groups performance comparison | Yes | Fixed interval and progressive interval | Discrete simple responses | Points exchangeable for money |

| Citation | Study number | Type of task | Procedure | Type of analysis | Control condition for RBIE | Reinforcement schedule | Nature of responses from participants | Nature of consequences |
|------------------------------|--------------|--|--------------------------------|---|----------------------------|---|---------------------------------------|-------------------------------|
| Joyce and Chase (1990) exp 1 | 18 | Reinforcement dependent on button presses | Unsignalled contingency change | Between groups performance comparison | Yes | Fixed ratio and fixed interval | Discrete simple responses | Points exchangeable for money |
| Kissi et al. (2018) | 19 | Conditional discrimination task | Unsignalled contingency change | Between groups performance comparison | Yes | Continuous | Discrete choice responses | Points |
| Kissi et al. (2021) exp 1 | 20 | Conditional discrimination task | Unsignalled contingency change | Between groups performance comparison | Yes | Intermittent | Discrete choice responses | Avoidance of painful stimuli |
| Kissi et al. (2021) exp 2 | 21 | Conditional discrimination task | Unsignalled contingency change | Between groups performance comparison | Yes | Intermittent | Discrete choice responses | Avoidance of painful stimuli |
| Kissi et al. (2021) exp 3 | 22 | Conditional discrimination task | Unsignalled contingency change | Between groups performance comparison | Yes | Intermittent | Discrete choice responses | Avoidance of painful stimuli |
| Miller et al. (2014) | 23 | Task in which average reinforcement interval could be minimised depending on responses | Unsignalled contingency change | Between groups performance comparison | No | Fixed interval and progressive interval | Discrete simple responses | Points exchangeable for money |
| Monestes et al. (2014) | 24 | Reinforcement dependent on button presses | Unsignalled contingency change | Parallel within groups performance comparison | Yes | Fixed interval and Fixed ratio | Discrete simple responses | Points |

| Citation | Study number | Type of task | Procedure | Type of analysis | Control condition for RBIE | Reinforcement schedule | Nature of responses from participants | Nature of consequences |
|------------------------------------|---------------------|--|--|---------------------------------------|-----------------------------------|---|--|---------------------------------------|
| Nergaard & Couto (2021) | 25 | Task in which average reinforcement interval could be minimised depending on responses | Unsignalled contingency change | Between groups performance comparison | No | Progressive interval and fixed interval | Discrete simple responses | Points exchangeable for money |
| Newman et al. (1994) | 26 | Conditional discrimination task | Unsignalled change in instruction accuracy | Between groups performance comparison | Yes | Fixed ratio | Discrete simple responses | Points |
| Newman et al. (1995) | 27 | Conditional discrimination task | Unsignalled change in instruction accuracy | Between groups performance comparison | No | Fixed ratio | Discrete simple responses | Points |
| Rosenfarb et al. (1993) | 28 | Reinforcement dependent on pattern of key presses | Unsignalled contingency change | Between groups performance comparison | Yes | Multiple schedules | Discrete simple responses | Points exchangeable for raffle ticket |
| Wulfert et al. (1994) experiment 1 | 29 | Reinforcement dependent on button presses | Unsignalled contingency change | Between groups performance comparison | Yes | Multiple schedules | Discrete simple responses | Points exchangeable for raffle ticket |

Table 5
Characteristics of Moderating Factors and Results

| Citation | Study number | Moderating factor | Experimental Conditions | Measure of RBIE | Results |
|-------------------------------|--------------|---|--|---|---|
| Baruche et al. (2007) | 1 | Depression and type of instruction given | <ol style="list-style-type: none"> 1. High scores on BDI (>12) and pliance 2. High scores on BDI and tracking 3. Low scores on BDI (<5) and pliance 4. High scores on BDI and tracking | Number of correct (schedule consistent) responses | <ul style="list-style-type: none"> • More schedule sensitive responses in high score groups ($mdn=38.0$) than low score groups ($mdn=0.8$)**. • More schedule sensitive responses in tracking conditions ($mdn=20.5$) than pliance ($mdn=4.5$)*. |
| Bern et al. (2021) | 2 | Coherence of a part of a mutually entailed relational network that was not relevant to task success | <ol style="list-style-type: none"> 1. High coherence 2. Low coherence 3. Control | <ul style="list-style-type: none"> • Number of rule consistent responses • Contingency sensitivity • Rule resurgence | <ul style="list-style-type: none"> • Rule-consistent responding higher in high coherence condition ($M=22.72$) compared to low coherence ($M=19.09$). • Participants in the high coherence condition took longer to show contingency sensitivity ($M=23.05$) than in the low coherence condition ($M=18.50$). • Greater resurgence of RGB in low coherence group ($Mdn=2.24$) compared with high coherence ($Mdn=0.00$). |
| deGrandpre and Buskist (1991) | 3 | Previous reinforcement history | <p>% of instructions that were accurate per trial block:</p> <ol style="list-style-type: none"> 1. 100-50-0 2. 0-50-100 3. 40-50-60 4. 60-50-40 | Percentage of rule-consistent responses in last 12 trials of block | <ul style="list-style-type: none"> • Rule consistent responding was higher during 50% condition when it followed the 100% condition ($M=79.2\%$) than when it followed the 0% ($M=43.3\%$) condition. • No reliable effects found in 40-50-60 and 60-50-40 groups. |

| Citation | Study number | Moderating factor | Experimental Conditions | Measure of RBIE | Results |
|-------------------------------------|--------------|--|--|---|---|
| Dixon and Hayes (1998) | 4 | Type of instruction given | <ol style="list-style-type: none"> Pliance Tracking Minimal instruction | <ul style="list-style-type: none"> Number of trials required to earn 80 reinforcers Resurgence of rule-consistent responding during extinction phase | No reported difference between pliance and tracking. Summary data not reported for this variable. |
| Donadelli & Strapasson (2015) exp 1 | 5 | Nature of consequential stimuli | <ol style="list-style-type: none"> Observer present Observer absent | Number of rule-consistent responses | Rule following reduced in the absence of experimenter/observer and was not reestablished by return of observer. No summary data reported. |
| Donadelli & Strapasson (2015) exp 3 | 6 | Nature of consequential stimuli | <ol style="list-style-type: none"> Verbal reprimand after first 10 trials in which rule was not followed Control | Number of rule-consistent responses | Rule following increased with introduction of social consequences. No summary data reported. |
| Fox and Pietras (2013) | 7 | Nature of consequential stimuli | <ol style="list-style-type: none"> Financial penalty for deviating from instructions Control | <p>“Switch point” when responding changed from PI to FI schedule.</p> | Switch points consistent with instructions more often in Penalty phase ($M=83.3\%$) than No Penalty Phase ($M=37.8\%$)* |
| Haas and Hayes (2006) | 8 | Effects of different types of feedback | <ol style="list-style-type: none"> Rule following feedback that reported rule-following regardless of behaviour Rule following feedback that reflected behaviour Rule following feedback that reported rule-following regardless of behaviour plus task performance feedback Rule following feedback that reflected behaviour plus task performance feedback | <ul style="list-style-type: none"> Rates of responding Number of participants who did not contact contingencies Number of participants who contacted contingencies and | <ul style="list-style-type: none"> Response rate in group 4 increased significantly less ($M=70.4$) than in group 6 ($M=170.8$) after contingency change from DRL to FR schedule ($d=1.294$)* More participants in group 4 (70%) showed either form of insensitivity than in any other group ($\leq 20\%$; Cohen’s $d = 1.28$)*** More participants in group 4 (50%) returned to rule following after contacting contingencies than in other groups combined (6%; Cohen’s $d = .91$)** |

| Citation | Study number | Moderating factor | Experimental Conditions | Measure of RBIE | Results |
|---------------------------|--------------|---------------------------------------|---|---|--|
| | | | 5. Rule alone control 6. Minimal rule controls | then reverted to rule following | <ul style="list-style-type: none"> No significant differences between groups when contingency changed from FR18 to yoked FI schedule. |
| Harte et al. (2017) exp 1 | 9 | Derivation | 1. Directly instructed rule 2. Derived rule | <ul style="list-style-type: none"> Number of rule consistent responses Contingency sensitivity | <ul style="list-style-type: none"> Number of rule consistent responses was higher in condition 1 ($M=19.78$) than in condition 2 ($M=17.55$) Contingency-consistent responding occurred after fewer trials in condition 2 ($M=19.45$) than in condition 1 ($M=21.33$) |
| Harte et al. (2017) exp 2 | 10 | Derivation | 1. Directly instructed rule 2. Derived rule 3. Control (Replication of study 9 with an increase in trials before contingency change from 10 to 100) | <ul style="list-style-type: none"> Number of rule consistent responses Contingency sensitivity | <ul style="list-style-type: none"> Number of rule-consistent responses was higher in group 1 ($M=31.09$) than group 2 ($M=19.27$)** or group 3 ($M=7.92$; $\eta^2 = .25$)** Participants required more trials before contingency-sensitive responding occurred in group 1 ($M=32.74$) compared to group 2 ($M=21.03$)** or 3 ($M=8.62$; $\eta^2 = .24$)** |
| Harte et al. (2018) exp 1 | 11 | Mutually entailed derivation of rules | 1. High derivation of rules (1 training block) 2. Low derivation of rules (15 training blocks) | <ul style="list-style-type: none"> Number of rule consistent responses Contingency sensitivity Rule resurgence | <ul style="list-style-type: none"> Number of rule consistent responses was higher in group 2 ($M=30.4$) than group 1 ($M=15.0$; Cohen's $d=1.03$)**. Participants required more trials before contingency-sensitive responding occurred in group 2 ($M=29.0$) compared to group 1 ($M=12.53$; Cohen's $d=1.21$)** No significant differences in rule resurgence between groups. |

| Citation | Study number | Moderating factor | Experimental Conditions | Measure of RBIE | Results |
|---------------------------|--------------|--|---|---|--|
| Harte et al. (2018) exp 2 | 12 | Combinatorially entailed derivation of rules | <ol style="list-style-type: none"> High derivation of rules (1 training block) Low derivation of rules (15 training blocks) | <ul style="list-style-type: none"> Number of rule consistent responses Contingency sensitivity Rule resurgence | <ul style="list-style-type: none"> Number of rule consistent responses was higher in group 2 ($M=21.74$) than group 1 ($M=13.5$; Cohen's $d=.56$)*. Participants required more trials before contingency-sensitive responding occurred in group 2 ($M=22.71$) compared to group 1 ($M=13.4$; Cohen's $d=.64$)** Rule resurgence was higher in group 1 ($M=9.18\%$) than group 2 ($M=4.68\%$). |
| Harte et al. (2020) exp 1 | 13 | Coherence altering feedback during training of A-B and B-C relations used to derive A-C rule. | <ol style="list-style-type: none"> Coherence increased through feedback No feedback | <ul style="list-style-type: none"> Number of rule consistent responses Contingency sensitivity Rule resurgence | <ul style="list-style-type: none"> Number of rule consistent responses was higher in group 1 ($M=19.97$) than in group 2 ($M=17.00$) Participants required more trials before contingency-sensitive responding occurred in group 1 ($M=18.33$) compared to group 2 ($M=14.40$) Rule resurgence was higher in group 2 ($Mdn=7.44$) than in group 1 ($Mdn=5.53$) |
| Harte et al. (2020) exp 2 | 14 | Coherence altering feedback during training of previously untrained A-C relations used to derive rule. | <ol style="list-style-type: none"> Coherence increased through feedback No feedback | <ul style="list-style-type: none"> Number of rule consistent responses Contingency sensitivity Rule resurgence | <ul style="list-style-type: none"> Number of rule consistent responses was higher in group 1 ($M=18.40$) than in group 2 ($M=15.56$) Participants required more trials before contingency-sensitive responding occurred in group 2 ($M=16.09$) compared to group 1 ($M=14.64$) Rule resurgence was higher in group 1 ($Mdn=5.41$) than in group 2 ($Mdn=4.65$; $r=.25$)* |

| Citation | Study number | Moderating factor | Experimental Conditions | Measure of RBIE | Results |
|---------------------------|--------------|--|---|---|--|
| Harte et al. (2021) Exp 1 | 15 | Coherence altering feedback during 160 trials of previously untrained A-C relations used to derive rule. | <ol style="list-style-type: none"> Coherence increased through feedback No Feedback | <ul style="list-style-type: none"> Number of rule consistent responses Contingency sensitivity Rule resurgence | <ul style="list-style-type: none"> Number of rule consistent responses was higher in group 2 ($M=18.33$) than in group 1 ($M=14.93$) Participants required more trials before contingency-sensitive responding occurred in group 2 ($M=17.07$) compared to group 1 ($M=14.73$) No discernible difference between groups for rule resurgence |
| Harte et al. (2021) Exp 2 | 16 | Coherence altering feedback during 32 trials of previously untrained A-C relations used to derive rule. | <ol style="list-style-type: none"> Coherence increased through feedback No feedback | <ul style="list-style-type: none"> Number of rule consistent responses Contingency sensitivity Rule resurgence | <ul style="list-style-type: none"> Number of rule consistent responses was higher in group 2 ($M=20.33$) than in group 1 ($M=13.03$) Participants required more trials before contingency-sensitive responding occurred in group 2 ($M=20.33$) compared to group 1 ($M=10.07$)** Rule resurgence was higher in group 1 ($Mdn=6.56\%$) than in group 2 ($Mdn=5.00\%$)* |
| Henley et al. (2017) | 17 | Type of instruction given | <ol style="list-style-type: none"> Directive rule ("you must") Non-directive rule ("you may consider") Generic rule ("the way to earn points is") | <ul style="list-style-type: none"> "Switch points" Points earned | Raw and descriptive data suggested that rule following was higher in groups 1 and 3 than group 2. |
| Joyce and Chase (1990) | 18 | Previous reinforcement history | <ol style="list-style-type: none"> Rule given after establishing schedule control Rule given without establishing schedule control Minimal instruction given after establishing schedule control | Ratio of responses per available reinforcer | Raw data suggested that no group showed changes in responses following contingency changes. |

| Citation | Study number | Moderating factor | Experimental Conditions | Measure of RBIE | Results |
|---------------------------|--------------|---------------------------|--|-------------------------------------|--|
| | | | 4. Minimal instruction given without establishing schedule control | | |
| Kissi et al. (2018) | 19 | Type of instruction given | <ol style="list-style-type: none"> 1. Rule expressed as ply 2. Rule expressed as track 3. No rule | Number of rule consistent responses | <ul style="list-style-type: none"> • Group 1 was more likely to give rule consistent responses after contingency switch than group 2*. • Group 3 was less likely to give rule consistent responses after contingency switch than groups 1*** or 2*** |
| Kissi et al. (2021) exp 1 | 20 | Type of instruction given | <ol style="list-style-type: none"> 1. Rule expressed as ply 2. Rule expressed as track 3. No rule | Number of rule consistent responses | <ul style="list-style-type: none"> • Group 1 gave more rule consistent responses after contingency change than group 2**. • Group 3 was less likely to give rule consistent responses after contingency switch than groups 1*** or 2* |
| Kissi et al. (2021) exp 2 | 21 | Type of instruction given | <ol style="list-style-type: none"> 1. Rule expressed as ply 2. Rule expressed as track 3. No rule | Number of rule consistent responses | <ul style="list-style-type: none"> • No reported difference between plys and tracks. Summary data not reported. • Group 3 was less likely to give rule consistent responses after contingency switch than groups 1*** or 2*** |
| Kissi et al. (2021) exp 3 | 22 | Type of instruction given | <ol style="list-style-type: none"> 1. Rule expressed as ply 2. Rule expressed as track 3. No rule | Number of rule consistent responses | <ul style="list-style-type: none"> • No reported difference between plys and tracks. Summary data not reported. • Group 3 was less likely to give rule consistent responses after contingency switch than groups 1*** or 2*** |

| Citation | Study number | Moderating factor | Experimental Conditions | Measure of RBIE | Results |
|-------------------------|--------------|---------------------------------|---|--|---|
| Miller et al. (2014) | 23 | Type of instruction given | <ol style="list-style-type: none"> 1. Directive mand ("you must") 2. Non-directive mand ("you might consider") | "Switch points" | <p>Raw data suggested that rule compliance was higher in group 1 than the group 2.</p> <ul style="list-style-type: none"> • Group 1a emitted more responses on a FR ($M=255.2$) schedule than a FI ($M=199.7$) schedule after contingency change • Group 1b emitted more responses on a FR ($M=406.6$) schedule than a FI ($M=199.3$) schedule after contingency change* |
| Monestes et al. (2014) | 24 | Diagnosis of delusions | <ol style="list-style-type: none"> 1. Instructions given <ol style="list-style-type: none"> a. Patients diagnosed with delusions b. Control 2. No instructions given <ol style="list-style-type: none"> a. Patients diagnosed with delusions b. Control 3. Self-generated instructions <ol style="list-style-type: none"> a. Patients diagnosed with delusions b. Control | Response rates on FR and FI aspects of a multiple schedule | <ul style="list-style-type: none"> • Group 3a emitted more responses on a FR ($M=216.2$) schedule than a FI ($M=167.8$) schedule after contingency change • Group 3b emitted more responses on a FR ($M=416.6$) schedule than a FI ($M=188.3$) schedule after contingency change** • Groups 2a and 2b both emitted more responses on FR than FI schedule after contingency change* |
| Nergaard & Couto (2021) | 25 | Nature of consequential stimuli | <ol style="list-style-type: none"> 1. Bonus points given for rule-consistent responding before contingency change 2. Points subtracted for rule-inconsistent responding before contingency change 3. Control | "Switch points" | <ul style="list-style-type: none"> • Raw and descriptive data revealed no clear difference between groups. • Number of rule-consistent switch points was highest in group 2 (98%), followed by group 1 (94%) and then group 3 (81%). • Changes across pre and post contingency change were minimal for all groups |

| Citation | Study number | Moderating factor | Experimental Conditions | Measure of RBIE | Results |
|-------------------------|--------------|------------------------|--|---|--|
| Newman et al. (1994) | 26 | Reinforcement Schedule | <ol style="list-style-type: none"> 1. FR1 schedule 2. FR2 schedule 3. FR3 schedule | Percentage of rule consistent responses | Raw data suggested responding was sensitive to changes in contingencies in group 1, but not in groups 2 or 3 |
| Newman et al. (1995) | 27 | Reinforcement Schedule | <ol style="list-style-type: none"> 1. FR1 schedule 2. FR2 schedule 3. FR3 schedule | Percentage of rule consistent responses | Raw data suggested responding was sensitive to changes in contingencies in group 1, but not in groups 2 or 3 |
| Rosenfarb et al. (1993) | 28 | Depression | <ol style="list-style-type: none"> 1. High scores (>15) on BDI <ol style="list-style-type: none"> a. Instruction given b. No instruction given 2. Low scores (<7) on BDI <ol style="list-style-type: none"> a. Instruction given b. No instruction given | Difference in response rates across FR and DRL aspects of multiple schedule | <ul style="list-style-type: none"> • Group 2a showed less difference in response rates than any other group* • No significant differences between groups 1a, 1b and 2b |
| Wulfert et al. (1994) | 29 | Psychological rigidity | <ol style="list-style-type: none"> 1. ≥75 %ile of screening sample on The Scale for Personality Rigidity 2. ≤ 25 %ile of screening sample on The Scale for Personality Rigidity | Difference in response rates across FR and DRL aspects of multiple schedule | Raw data suggested that group 1 showed less schedule sensitivity than group 2 |

Note: * $p < .05$, ** $p < .01$, *** $p < .001$

Quality assessment

Four studies were assessed as being of Moderate quality, randomised trials downgraded from High due to risk of bias related to sampling and blinding. Eleven studies were assessed as being of Low Quality, predominantly due high risk of bias and selective reporting. Fourteen studies were assessed as being of Very Low quality, predominantly due to high risk of bias due to lack of randomisation or unclear randomisation and blinding, lack of systematic analytical methods and selective reporting. This quality assessment was used to inform the syntheses and interpretation of results.

Moderating Factors Associated with Rule Based Insensitivity

A range of potential moderating factors of the RBIE were investigated in the studies included in this review including derivation of rules, coherence of rules, psychological variables, rule topography, nature of consequential stimuli, reinforcement schedules, and historic rule accuracy.

Derivation

“Derivation” refers to the process by which training a set of stimulus relations gives rise to novel and previously untrained stimulus relations. The level of derivation can be regarded as high if a relation has only recently been derived, or low if it has been derived on many subsequent occasions (Barnes-Holmes et al., 2017). Studies 8, 9, 10, 11 and 12 considered the effects of derivation on RGB. Studies 10, 11 and 12 found that higher levels of derivation were associated with a significant reduction in RBI both in term of number of rule-consistent responses and the number of trials required before participants showed contingency sensitive responding. This was not significant in Study 9, reaching significance when the same procedure was replicated in Study 10 which increased the number of trials from 10 to 80 ($\eta^2=.24-.25$). Studies 9 and 10 used direct instruction as a form of very low derivation rule and compared this with a rule derived from novel stimuli. Across Studies 11 and 12 the number of training trials employed was manipulated to vary levels of derivation. Studies 11 and 12 found that both mutually and combinatorially entailed derivation influenced the RBIE, with larger effects found for mutually entailed derivation (Cohen’s $d=1.03-1.21$) than combinatorially entailed derivation

(Cohen's $d=.56-.64$). Studies 9-12 all used similar procedures and were all assessed as Low quality.

Study 8 differed in procedures in that it examined the interaction between task-oriented feedback and performance contingent feedback, finding that RBI was significantly increased when both were present compared to being presented in isolation or not at all (Cohen's $d=.91-1.30$ depending on measurement chosen for RBI). It was argued that when both types of feedback were present a derived relation was created between feedback on rule breaking and point scoring resulting in points, typically a reinforcing consequence, being transformed to have an aversive stimulus function through coordination with a typically punishing consequence, namely feedback on rule breaking. As such this has been included as an indirect investigation of derivation.

Large effect sizes mitigate the quality of the evidence to some degree, however this remains a small number of low quality studies at high risk of bias. As such the overall confidence in this finding is Low, meaning that the the true effect may be substantially different from those reported.

Coherence

“Coherence” refers to the degree of overlap, or the logical consistency, between different reinforced patterns of AARRing. Five low quality randomised trials (Studies 2, 13, 14, 15 and 16) investigated levels of coherence as a moderating factor. All studies used feedback on rule following as a means of varying coherence within a derived relational network, with Studies 13-16 manipulating the coherence of the derived rule and Study 2 manipulating the coherence of a part of the relational network that was not necessary to derive the required rule. No studies found significant differences in rule compliance across conditions of high and low coherence and if considering just the direction of effects results remain conflicted.

As well as rates of rule compliance, a number of other measures of the RBIE were analysed across these studies. Studies 14 and 16 found greater resurgence of rule-consistent responses after contingencies were contacted when coherence was increased ($r=.25$ in Study 14). Study 16 also found that participants for whom coherence was increased via feedback emitted contingency consistent

behaviour sooner than those who received no feedback ($p < .001$) which suggests that increasing coherence reduced, rather than increased, RBI when using this definition.

Overall, preliminary evidence suggests that higher levels of coherence may increase the speed of adaptation to changed contingencies, but may also lead to greater subsequent resurgence of rule-consistent responding. The evidence does not indicate that coherence moderates absolute rates of rule following. Considering the low quality of studies and conflicting results, there is Low confidence in these findings and the true effects may be substantially different from those reported.

Psychological Suffering

Four quasi-experimental trials (Studies 1, 24, 28 and 29) considered the role of mental health or related psychological factors as a moderating factor of the RBIE. Study 1 and 28 used the Beck Depression Inventory (BDI: Beck et al., 1961) to group participants into high and low scoring experimental conditions. Both studies found significantly higher rates of schedule sensitive responding after contingency changes in the “depressed/dysphoric” participants compared with participants scoring low on the BDI. However, Study 1 did not include a no-instructions condition so it is not clear whether differences between groups were due to the presence of a verbal rule. Quality of studies was Low, however, so results should be interpreted with caution.

Study 24 investigated RBI in psychiatric inpatients diagnosed with delusions as compared to college student controls, finding an opposing effect to Studies 1 and 28. Psychiatric inpatients were not found to respond significantly differently to fixed ratio and fixed interval components of a multiple schedule of reinforcement after a contingency change ($p = .463$), despite doing so when instructions were accurate ($p = .027$), while controls did ($p = .036$). Psychiatric controls without verbal instructions did show differential responding across the components of the multiple schedule ($p = .043$). However, groups were not directly compared across measures of RBI and the quality of this study was Very Low.

Study 29 found that participants scoring high on the Scale for Personality Rigidity exhibited a greater RBIE than low scoring participants. Statistical analysis was not conducted, and this study was

rated as Very Low quality due to sample size, lack of generalisability from the convenience sample and lack of randomisation.

While all four trials found preliminary evidence for psychological suffering moderating RBI, the overall quality of the evidence was judged to be Very Low, and the true effect is likely to be substantially different to that found.

Rule Type

Studies 1, 4, 19, 20,21 and 22 compared the effect of pliance and tracking on RBI. Studies 1, 19 and 20 found that pliance resulted in greater RBI than tracking, although this only reached significance in Study 19 ($p < .05$) and 20 ($p < .01$). Study 4 found no significant effect, although it was the smallest of the studies investigating tracking and pliance and Very Low quality. Studies 21 and 22 reported ceiling effects in both pliance and tracking conditions, finding no significant differences ($ps > .05$) between groups.

Studies 17 and 23 found greater RBI when rules were presented with the mand “you must” compared with “you might consider”, which were assumed to imply social and environmental mediation of consequences respectively. Significance testing was not conducted in either study, with conclusions drawn from observations of descriptive data.

Four Moderate quality experiments (19, 20, 21, 22), one Low, and one Very Low quality experiment compared the effects of tracking and pliance on RBI. Where differences were found they all indicated that pliance was more strongly associated with RBI than tracking, and where no differences were found methodological issues may have obscured effects. Despite the presence of several moderate quality studies, confidence in this finding was rated as Low since effect size estimates were not available from Studies 19 and 20 to be able to consider the relative importance of rule type as a moderator of RBI.

Consequences of Following or Deviating from Rules

Studies 5 and 6 found that actual or perceived social consequences of rule following may affect

rule-based insensitivity, although this was not analysed statistically. In Study 5 there was evidence of RBI when an observer was present which reduced when the observer was removed. The return of the observer did not re-establish rule following, and it was hypothesised that this was because anticipated social consequences were not enacted. In Study 6, which used near identical procedures, a verbal reprimand was given by the observer when rules were not followed which increased rule following.

Study 7 found that a financial penalty for rule breaking significantly increased rule-following even though overall financial reward remained greater for rule-breaking behaviour than for rule-following. However, this was based on analysis of only four participants. Study 25 concluded that there was no discernible difference between punishment and reward in terms of influence on the RBIE but also conducted no statistical analysis.

All four experiments into consequential stimuli as a moderator of RBI were rated as Very Low quality. While the evidence suggests that nature of consequences may moderate the RBIE, we have Very Low confidence in this outcome and the true effect is likely to be substantially different to those reported.

Reinforcement Schedule

Studies 26 and 27 both found that RBI was not evident under a schedule of continuous reinforcement, while it was under fixed ratio one and fixed ratio two schedules. In Study 27 qualitative data suggested that participants attempted to self-generate rules and found they were able to test and confirm these when a continuous reinforcement schedule was in place but not under lower rates of reinforcement. However, the quality of evidence for this outcome was Very Low. It is notable that several higher quality studies included in this review used continuous reinforcement schedules and found statistically significant effects for moderators of RBI (Studies 2, 11, 12, 13, 15, 20). Overall, there is Very Low confidence in these findings, and it is not possible to say with any certainty that reinforcement schedule is a moderating factor for RBI.

Previous Reinforcement History

Two studies considered previous reinforcement histories as a moderator of the RBIE. Study 3 found that a learning history that included inaccurate instructions given by the experimenter reduced the RBIE compared to a history of solely accurate instructions. Study 18 considered whether establishing schedule control prior to providing a verbal rule moderated the RBIE, finding that schedule-controlled behaviour was not evident in either experimental condition. Neither study tested the significance of their findings and both were rated as Very Low quality. Overall, we have Very Low confidence in findings that previous reinforcement histories may moderate RBI.

Discussion

This review considered the evidence for factors that may moderate rule-based insensitivity. While multiple studies found preliminary evidence for a number of factors, confidence in findings was low or very low. The findings of this review suggest that (a) there is preliminary evidence for a larger rule-based insensitivity effect when verbal rules are characterised by low levels of derivation and high levels of coherence, however the true effect is likely to be substantially different to reported effects (b) there is preliminary evidence that pliance is associated with a larger rule-based insensitivity effect than tracking, but the true effect is likely to be substantially different to reported effects (c) it is not possible to say with any confidence that psychological suffering, reinforcement schedule, previous reinforcement history or the nature of consequential stimuli moderate the rule-based insensitivity effect.

Derivation

Low quality evidence from three studies (10, 11, 12) suggested that where there have been more opportunities to derive a rule it may be adhered to more rigidly, and Study 8 provided indirect and low quality evidence that RBI may be moderated by the coordination of different consequences rather than the consequences themselves. Empirical research has historically explored RBI and AARR separately,

but theoretically their interaction has been viewed as critical to understanding RGB (Hayes et al., 2001, 2012; Sidman, 1994) and drawing links between RFT research and applied practice (Barnes-Holmes et al., 2017). For example, if reducing derivation increases RBI, this may help develop technical descriptions of how psychological rigidity and flexibility are related to a person's learning history. Clinically, this may provide an adjunctive means of assessing "fusion" with verbal content (in terms of the historic opportunities to derive a particular rule and the anticipated resulting degree of RBI), and intervention planning (in terms of increasing the number and frequency of opportunities for more helpful rules to be derived). It has previously been suggested that the value of experiential learning in clinical practice is that it facilitates the derivation of verbal discriminations, or deictic relational frames, in which the self is located "here and now" and aversive thoughts and feelings are located "there and then" (Törneke et al., 2008). The present evidence lends preliminary empirical support to the value of facilitating the derivation of these relations rather than directly instructing them, although higher quality evidence is needed in order to understand the relationship between derivation and RBI.

Coherence

The evidence relating to coherence found no significant relationships with absolute rates of rule compliance. There were differences found in how many trials were required before participants showed schedule sensitive responding and how likely it was for RGB to resurge after contacting contingencies, with higher coherence being associated with more rapid contact with changed contingencies (Study 16) but more likelihood of subsequently returning to the now inaccurate rule (Study 14 and 16). While there was Low confidence in this finding, it suggests that the relationship between RGB and AARR may not be a straightforward one. These findings also highlight a need for consensus in how RBI is defined in order to make meaningful comparisons across different studies.

Coherence is regarded within RFT as a generalised reinforcer, established as such by social reinforcement of internally and logically consistent verbal behaviour (Blackledge et al., 2009; Törneke, 2010). One theorised consequence of this is that once a coherent narrative or rule is established, efforts

will be made to protect and maintain coherence and consistency since incoherence is experienced as punishing (Törneke, 2010). This provides a potential interpretation of why rule-resurgence was associated with increased coherence. Participants were perhaps not truly “insensitive” to changed contingencies, but rather experienced contact with them as aversive when they challenged coherence. If this finding were replicated in more robust trials, it offers a possible conceptualisation of many therapeutic techniques such as shifting perspectives in terms of reducing the coherence of unhelpful verbal behaviours to establish them as aversive.

Overall, these findings lend preliminary support to the hypothesis that AARR is associated with rule-governed behaviour (Hayes et al., 2001, 2012; Sidman, 1994), albeit in a manner that is not necessarily captured in simple counts of rule consistent behaviour.

Psychological Suffering

Four studies were identified that investigated psychological suffering as a moderating factor for RBI (Studies 1, 24, 28, 29). Studies 1 and 28 considered depression as a moderating factor, however Study 1 did not include a no-instructions condition to assess whether any group differences were due to the presence of a verbal rule. Study 28 provided low quality evidence that depression may be associated with reduced rule-following after a contingency change, contradicting the theoretical literature associating psychological suffering with increased RBI (e.g. Hayes et al., 2012). This finding appeals to the “depressive realism” literature (see Moore & Fresco, 2012 for a review), although well-powered studies have failed to find evidence for this phenomenon (Dev et al., 2022). It has been suggested that psychological suffering may be related to successful tracking of short-term consequences, for example reduced distress as a consequence of social withdrawal, but ineffective tracking of longer term social, emotional and functional consequences (Törneke et al., 2008). It is possible that in Study 28 depressed participants were in fact very effective at tracking short term correspondence between rules and contingencies while non-depressed participants were more prone to augmenting short-term tracking with longer term rules regarding the inter- or intra-personal

consequences of rule-breakage. This may have reduced the influence of short-term reinforcers such as point acquisition for non-depressed participants but not depressed participants. If so, this may indicate that treatment goals for depression should not focus on increasing short-term contingency sensitivity, but rather increasing use of augmenting and tracking of long-term contingencies.

Study 24 found preliminary evidence for increased rule-following among patients with delusions, however direct comparisons were not made between participants with and without delusions. As such it is not possible to say with any certainty that RBI is moderated by delusional beliefs and there is a need for further research into a possible relationship between RBI and delusions.

Overall there is Very Low confidence in findings that psychological suffering is moderated by RBI. Theoretically, RBI has been posited as an explanation for psychological suffering (Hayes et al., 2012), however this is currently not well supported in the empirical literature.

Type of Rule

Low-moderate quality evidence suggested that pliance exerts a greater influence on RBIE than tracking (Studies 1, 19, 20). The null hypothesis was accepted in two moderate quality studies (21, 22), however ceiling effects in the measurement of RBI suggest that findings are not representative of the true effect. A further three studies were not of sufficient quality to draw conclusions from with any confidence (4, 17, 23).

These findings correspond with theoretical RFT literature which suggests pliance is more associated with insensitivity than tracking since the intended function of socially mediated consequences is to remove the need for the person receiving the rule to experience direct consequences associated with a behaviour (Hayes et al., 2012; Törneke, 2010). While experimental research regarding pliance and tracking is scarce, psychometric tools for assessing features of pliance correlate with measures of depression and dysfunctional attitudes, and experiential avoidance (Ruiz et al., 2019). However, the literature surrounding the role of tracking and pliance in the RBI is very limited at present, consistent with findings from previous reviews (Kissi et al., 2017), and no studies were

identified which investigated augmenting.

Nature of Consequential Stimuli

The nature of consequential stimuli was considered across four studies finding that rule following was increased in the context of reward (Study 25), punishment (Study 7, 25), presence of an observer (Study 5), and verbal reprimands regarding rule compliance (Study 6). All studies were Very Low in quality and it is not possible to say with any confidence that the nature of consequential stimuli is a moderator of RBI. Nonetheless, these findings are consistent with basic behavioural principles which posit RGB as an operant behaviour (Sturmev et al., 2020) and long established evidence of observer effects in experimental research (e.g. Kazdin, 1982).

Reinforcement Schedule

Two Very Low quality studies (26, 27) considered reinforcement schedule as a moderator of RBI. High risk of bias in these studies and a lack of systematic analysis means that it was not possible to conclude with any confidence that reinforcement schedule moderates RBI. It is notable that the finding that RBI was not apparent under conditions of continuous reinforcement appears to be contradicted in numerous higher quality studies identified in this review (Studies 1, 9, 10, 11, 12, 15, 16, 19).

Although not an outcome relevant to the present research question, Study 27 included qualitative data from participants which suggested participants were self-generating and testing alternative verbal rules after contingency changes. It has previously been found that even when provided with no instruction participants often self-generate rules (Rosenfarb et al., 1992), serving as a reminder to researchers that it cannot reliably be assumed that behaviour that appears to correspond with direct contingencies is purely schedule-governed.

Reinforcement History

Two studies (Study 3 and 18) explored reinforcement history as a moderator of RBI. Both studies were of Very Low quality and neither included systematic analysis of results. In Study 18 it is

also hard to see that participants would have contacted changes in contingencies given that changes in reinforcement rate were marginal. As such, it is not possible to say with any confidence that reinforcement history moderates RBI. From a conceptual perspective a relationship between reinforcement history and RBI would be expected. RBI is considered to be an operantly learned behaviour mediated by the perceived credibility of the person uttering a rule (Törneke, 2010). If this is the case, a history of accurate or inaccurate instructions from a particular speaker would be expected to influence the degree to which a rule is followed and higher quality research testing this hypothesis would be welcomed.

Limitations

For this review rule-governed behaviour was defined as behaviour that predominantly corresponded with consequential stimuli as opposed to verbal rules generated within the experiment. One limitation of this, identified in a small number of studies (e.g. Newman et al., 1995), is that it does not rule out instructional control of apparently schedule-sensitive behaviour. If participants were self-generating private rules, or behaving in accordance with pre-established rules, then findings would not strictly reflect a comparison of rule-based and schedule-based behaviour. However, where behaviour changes following a contingency change it strengthens confidence in it being schedule-sensitive (Hayes et al., 1986).

The nature of this review is also such that estimates of effect size cannot be made. More stringent exclusion criteria on the basis of data reported, and on how contingency sensitive and insensitive behaviour is operationalised and measured, may have facilitated a quantitative synthesis. Additionally, narrative synthesis of results can lead to lower quality evidence being given too much weight in conclusions and abstracts (Boutron et al., 2019) which should be considered by readers of this review. However, a lack of consensus regarding the measurement and definition of contingency sensitive and insensitive behaviour (Kissi et al., 2020) presents a challenge for quantitative synthesis.

For some moderating factors, for example derivation, all studies found results in the same

direction. Typically, when this is found during a systematic review it is indicative of publication bias (Chan et al., 2014; Thornton & Lee, 2000) and the consequent risk that the existence of an effect is overestimated should be considered when interpreting these results. Including unpublished theses, book chapters, and conference abstracts in this review may have highlighted additional research and mitigated the impact of publication bias (Boutron et al., 2019).

Future Research Directions

First and foremost, this review highlights the paucity of research into factors moderating rule-based insensitivity. High quality trials investigating potential moderators might build initially on the preliminary findings here. It would be beneficial, given the low confidence in findings for any of the potential moderating variables, for future research to initially aim for consistency in methods and outcomes in order to demonstrate reliable effects before considering any further exploration of these factors. If reliable effects can be established, a particularly pertinent area for future research would be the relationship between psychological suffering and RBI. This would provide an important bridge between the current RFT research and applied practice. Finally, a notable omission in the research into how different types of rules interact with RBI is augmenting. Given the proposed importance of facilitating effective augmenting in ACT, this represents another area in which high quality empirical research would be beneficial for establishing robust links between the theoretical assumptions of RFT and clinical practice.

Conclusions

Rule-based insensitivity is argued to play an important role in the development and maintenance of psychological suffering. Despite the existence of this effect being demonstrated empirically, this review suggests that claims as to how this effect might be influenced in practice are not well supported. No strong evidence was identified for any moderating factors of rule-based insensitivity, although preliminary evidence emerged to suggest that coherence, derivation and type of rule may be relevant. It is therefore recommended that high quality trials consider moderators of

the rule-based insensitivity effect to examine its relevance to theoretical and practical approaches to psychological suffering.

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A thematic analysis of the functions of sleep-wake reversal in the context of psychosis

Stuart Ivory (North Wales Clinical Psychology Programme), Robin Owen (Betsi Cadwaladr University Health Board), Mike Jackson (North Wales Clinical Psychology Programme)

Corresponding author: Stuart Ivory, stuart.ivory@nhs.net

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Abstract

Sleep problems affect a majority of individuals with psychosis and are associated with worse clinical, functional and social outcomes. Research has shown that sleep problems may have a causal role in the maintenance and development of psychotic experiences and that sleep is an efficacious treatment target for reducing hallucinations and delusions. Despite its relevance to a large number of people with psychosis, research to date has not focused on the experiences of people with sleep-wake reversal and psychosis. This study aimed to explore the intended functions of behaviours associated with sleep-wake reversal comorbid with psychosis from a Functional Contextualist perspective.

Interview data from five individuals with experiences of sleep-wake reversal and psychosis was analysed using Thematic Analysis. Participants described difficulties with sleep emerging from a context of social isolation, loss of occupation, and difficulty making sense of psychosis. Participants described a fear of sleep due to nightmares, vivid dreams and a worsening of hallucinations. This frequently led to an avoidance of sleep at night. In contrast, daytime sleep was often viewed as desirable as it offered an escape from paranoia, low mood and social interaction. Lack of occupation and boredom provided a context in which sleep disturbance was maintained even when psychotic experiences were managed well. It is recommended that interventions for sleep-wake reversal in the context of psychosis are based on robust assessment of the contexts in which sleep disturbance occurs and facilitate engagement in meaningful activity and relationships.

Keywords: sleep, psychosis, schizophrenia, qualitative, thematic analysis, functional contextualism, circadian rhythm disorder

Introduction

Sleep disturbance affects up to 80% of people with psychosis (Reeve et al., 2019), with insomnia alone affecting over half of patients with a diagnosis of schizophrenia (Freeman et al., 2019). The importance of sleep disturbance in clinical practice is hard to understate, being associated with reduced mood and quality of life, increased anxiety, fatigue and symptom severity, and increased risk of suicide and suicidal ideation (Koyanagi & Stickley, 2015; Li et al., 2016; Miller et al., 2019; Reeve et al., 2019). Notably, associations between sleep disturbance and psychological difficulties persist once mood is controlled for (Zaks et al., 2022). Sleep disturbance is also associated with a number of long term health consequences such as hypertension, diabetes, obesity, heart attack and stroke (Colten et al., 2006). Despite this, people with psychosis are rarely offered sleep interventions in line with clinical guidelines (Reeve et al., 2019).

While sleep disruption was historically considered a consequence of psychosis (e.g. Chouinard et al., 2004), there has been increasing evidence to suggest that sleep disturbance may be a causal factor for psychotic experiences (Freeman et al., 2017; Yates, 2016). Longitudinal research has found that sleep problems are associated with up to 4 times greater odds of reporting hallucinations (Sheaves et al., 2016), and increase the odds that someone will report psychotic experiences in future (Sheaves et al., 2016; Thompson et al., 2015). Furthermore, treating insomnia can reduce experiences of paranoia and hallucinations (Freeman et al., 2017) suggesting a causal link. A review of the literature found that sleep disturbance predicts both the onset and persistence of psychotic symptoms, and that psychological interventions for sleep problems are effective in the management of both sleep problems and psychotic symptoms (Reeve et al., 2015).

The negative effect of sleep disorders on functioning for people with psychosis is well documented (e.g. Faulkner & Bee, 2017; Waite, Evans, et al., 2016) and individuals with psychosis

have been found to be motivated to engage with treatment for sleep difficulties (Waite, Evans, et al., 2016; Waite et al., 2020). However, sleep dysfunction may also have negatively reinforcing functions for people with psychosis such as offering an escape from unwanted experiences (Faulkner & Bee, 2017). The literature regarding sleep difficulties comorbid with psychosis has tended to focus on environmental and biological factors (e.g. Taylor et al., 2015; Waters & Manoach, 2012), although the efficacy of Cognitive Behavioural Therapy for Insomnia (CBT-I) for people with psychosis (Freeman et al., 2015, 2017; Hwang et al., 2019) highlights an important role of cognitive and behavioural factors. Faulkner and Bee's (2017) finding that sleep is sometimes seen as an escape from distress, although not explored in depth, suggests that sleep disturbance in the context of psychosis may involve cognitive and behavioural factors that are distinct from those typically associated with insomnia.

Within a Functional Contextualist framework, behaviour is analysed in terms of how it functions in specific present and historical contexts (Hayes et al., 2012; Törneke, 2010), offering a framework for considering the relationship between sleep-related behaviours and psychosis. Functional Contextualism underpins Relational Frame Theory (RFT; Hayes et al., 2001; Törneke, 2010) and in turn Acceptance and Commitment Therapy (ACT; Harris, 2019; Hayes et al., 2012), the successes of which illustrate the potential value of this perspective on psychological distress (Arch et al., 2012; A-Tjak et al., 2015; Bach et al., 2012; Bai et al., 2020; Byrne et al., 2019; Wakefield et al., 2018). Previous qualitative accounts of sleep experiences among people with psychosis have understandably focused on the drawbacks of sleep disruption and perspectives on treatment (e.g. Faulkner & Bee, 2017). However, understanding factors that might reinforce and maintain sleep disturbance contributes to a more complete understanding of how these patterns of behaviour arise which can enhance the development of interventions.

Avoidance of unwanted private experiences has been hypothesised to be an important function in several behaviours common in psychosis, for example verbal behaviours such as delusions and withdrawal from daily life activities (O'Donoghue et al., 2018). This raises a question as to whether

similar functions may be relevant to sleep disturbance. If this is the case, then interventions focused on reducing avoidance may also improve sleep. These functions might be anticipated to be most prominent when sleep is characterised by difficulties such as sleep-wake reversal. Sleep-wake reversal is being defined here as markedly delayed or advanced sleep-wake timings as compared to typical bedtime and waking times, to the extent that at least half of the main sleep period falls between typical waking hours. Typical waking hours are being considered as between 7 o'clock in the morning and 9 o'clock in the evening (Duffy et al., 2001). A choice has been made not to adopt psychiatric or medical diagnostic labels to describe participants' sleep patterns in order to avoid conferring assumptions about aetiology and presentation that are not necessarily being made within the current exploration of functional aspects of behaviour. Previous research indicates that sleep-wake reversal is a relatively common presentation among people with psychosis (Reeve et al., 2019; Wulff et al., 2012). It is notable in this regard that different profiles of sleep disturbance respond differently to CBT-I when investigated in the context of psychosis (Chiu et al., 2018), highlighting the need to understand different aspects of sleep disturbance in order to effectively tailor interventions. However, much of the literature focuses on people who meet the criteria for a diagnosis of insomnia, with difficulties such as sleep-wake reversal receiving less attention.

Clinical experience suggests that sleep-wake reversal may affect a significant number of people with psychosis. However, empirical support for this is spread across several strands of research. One area of research to consider relates to circadian rhythms and sleep-wake phase disorders. Little large-scale research exists in relation to delayed sleep phases among people with psychosis (Klingaman et al., 2015) and prevalence estimates vary widely. Estimates of circadian rhythm disorder prevalence among people with psychosis range from 8.3% (Reeve et al., 2019) to as high as 50% for delayed sleep phase disorder (Wulff et al., 2012). While circadian rhythm disorders such as delayed sleep phase disorder have a putative biological aetiology, misdiagnosis is common which suggests that misalignment between desired and actual sleep timings may often have psychosocial or behavioural

causes (Murray et al., 2017). Another relevant area of research is that regarding daytime sleepiness. Daytime sleepiness has received relatively little research attention in comparison to other sleep difficulties, even within the context of mood disorders where hypersomnia is a common difficulty (Kaplan & Harvey, 2009). One recent study reported a 23% prevalence rate for excessive daytime sleepiness among a sample of people with early psychosis, with most reporting comorbid sleep disturbances such as insomnia (Reeve et al., 2019). Daytime sleepiness among people with psychosis is often attributed to side effects of anti-psychotic medication, however, preliminary cross-sectional research has found no differences in daytime sleepiness across medication types and dosages (Reeve et al., 2021). Although specific prevalence estimates could not be found for sleep-wake reversal as a unitary construct, together the evidence suggests that a significant minority of individuals with psychosis struggle with daytime sleepiness, night-time sleep disturbance and misalignment of desired and actual sleep timings. While in some cases this may be attributed to altered timing of melatonin production (Wulff et al., 2012) or medication side-effects (Tandon et al., 2020), the robustness of these proposals has been challenged and it is important to consider alternative explanations (Murray et al., 2017; Reeve et al., 2021).

The aim of this study was therefore to qualitatively explore possible functions of behaviours associated with sleep-wake reversal among people with psychosis. Sleep-wake reversal was chosen as a specific topic of study as it represents a particularly stark example of sleep behaviour that distances people from daily life activities.

Method

Ethical Approval

Ethical approval for this research was obtained from the Social Care NHS Research Ethics Committee (22/IEC08/0041), and a local health board approved Capacity and Capability to act as a Participant Identification Centre.

Methodology

A qualitative methodology was employed as it offers an opportunity to explore topics in depth that have not been well studied and to develop detailed descriptions of people's experiences (Braun & Clarke, 2013). Specifically, Thematic Analysis (TA), using Braun and Clarke's reflexive approach (Braun & Clarke, 2006) was chosen due to its flexibility and ability to produce theoretically informed interpretations of patterns in data where there is relative heterogeneity in the experiences of participants (Braun & Clarke, 2021).

Recruitment

Seven participants were recruited through NHS outpatient mental health teams. Care-coordinators were asked to make an initial approach to adults assessed as having experiences of sleep-wake reversal and psychosis within the past three years. The decision to include people with both past and current experiences of sleep-wake reversal and psychosis was made in part because people may make sense of their experiences differently depending on their current relationship with psychological and behavioural difficulties, offering a broader and more in-depth analysis of a topic that has received little research attention to date. There was also a pragmatic consideration that contacting people currently experiencing sleep-wake reversal can be challenging due to the timing of their sleep.

Participants were provided with an information sheet prior to giving written consent to participate. A £20 shopping voucher was offered in return for attending an interview. Initial recruitment was carried out between February and April 2023 and six participants consented to be contacted by the research team. Further recruitment was carried out between July and September 2023 which resulted in a three additional prospective participants consenting to be contacted by the research team. Seven participants attended an interview in total. One prospective participant did not proceed beyond preliminary discussions due to a deterioration in their mental health, and one cancelled their interview due to time constraints after securing employment.

Inclusion and Exclusion Criteria

The inclusion criteria for this study were that participants: were identified by their care-coordinator as having experienced a period of clinically significant sleep disturbance within the past three years during which at least half of their main sleep period was typically falling between the hours of seven o'clock in the morning and nine o'clock in the evening; had been assessed by their healthcare provider as experiencing an episode of psychosis within the past three years; were not currently assessed by their healthcare team as lacking the mental capacity to consent to participate in research; were living in the community and; were over the age of 18. The exclusion criteria would be met if: a participant was below 18 years of age; a participant had been assessed as currently lacking mental capacity to give consent to participate in research; a participant was currently receiving inpatient mental healthcare; or experiences of psychosis or sleep-wake reversal were secondary to a physical health problem e.g. traumatic brain injury or neurodegenerative disease.

Data Collection

Individual semi-structured interviews were conducted by the first author (mean duration = 63 minutes, range = 41-82 minutes). A semi-structured interview schedule (Appendix III) was developed in conjunction with clinicians experienced in supporting people with psychosis and drawing on functional analysis interview frameworks (e.g. Functional Assessment Interview; O'Neill et al., 2015). The interview schedule asked open-ended questions about participants' experiences of mental health difficulties and sleep, and ways in which different sleep patterns had functioned in their lives. The interview schedule was piloted with a non-clinical volunteer who had lived experience of subjective sleep disturbance and mental health difficulties. No amendments were made to the schedule following the pilot.

Interviews were conducted at participants' homes (n=3) or via video conference software (n=4), depending on participant preference. Interviews were audio recorded and transcribed verbatim by the first author for analysis, with identifying details anonymised. The first and third authors were not a

member of any of the healthcare teams involved in the study. The second author had worked clinically with three participants who were fully informed about their involvement in the study.

Analysis

Data were analysed by the first author using Braun and Clarke's (2006) 6-stage process of reflexive thematic analysis (TA). This involved familiarisation and immersion in the data followed by "complete coding" whereby any extracts from the data relevant to the research question were given initial codes. Transcripts were then reread, and further codes and annotations created. Initial themes were then generated from codes as part of an iterative process of generating potential themes, checking candidate themes against the transcript data, and revising themes. Candidate themes were further reviewed and refined through discussion within the research team which facilitated reflection on assumptions and interpretations being made by the first author. Participants had been invited to review and comment on proposed themes, with two agreeing to do so. A summary of candidate themes was sent by email to these participants with an invitation to comment on the credibility of themes, with neither participant suggesting substantive changes. Themes were then defined and named before findings were written up, supported by extracts from the data. The NVivo software package (QSR International Pty Ltd., 2018) was used to organise and manage data and codes.

Epistemological and Theoretical Position

This thematic analysis was theoretically rooted in Functional Contextualism. In contrast with more mechanistic philosophies, Functional Contextualism is a pragmatic philosophy that judges the validity of an explanation on its usefulness in predicting and influencing behaviour (Hayes et al., 2012), recognising that different explanations might be more or less useful in different contexts (Herbert & Padovani, 2015). This theoretical stance was adopted since it facilitated an analysis of how topographically similar sleep behaviours may serve different, contextually bound, functions.

Epistemologically, a contextualist approach assumes that knowledge arises from context and is thus always situated and provisional (Madill et al., 2000). Participant accounts were therefore considered to represent a true reflection of their reality within a certain context.

Reflexive Statement

The first author is a white, English male Trainee Clinical Psychologist. He does not have lived experience of psychosis or sleep reversal, however a family member struggled with both for many years. All three authors have worked with people with psychosis in their clinical roles. The first and second authors both use Acceptance and Commitment Therapy in their clinical roles, which contributed to the decision to frame the data within a Functional Contextualist paradigm. However, this could also have introduced a bias towards overfitting data to this theory. The third author is an experienced clinician whose practice drew on different therapeutic models, allowing them to offer an alternative perspective which facilitated a richer analysis.

A reflexive journal was kept by the first author throughout the data collection and analysis process. This allowed for assumptions, impressions and personal reactions to the data to be made explicit. Initial thematic maps closely mirrored typical behavioural formulations of psychological suffering and an urge to identify causal relationships was noted. Exploration of how the authors experiences as a clinician had influenced theme development led to an alternative analysis that was closer to the data and less shaped by established formulation models.

Results

Seven participants (two female, five male) participated in this study, representing a small sample for a TA project (Braun & Clarke, 2013). Participants were all in their 20s or 30s. Six participants reported having received diagnoses of Schizophrenia and one had experienced a First Episode of Psychosis. Specific self-reported difficulties commonly included hallucinations (N=6), delusions (n=7) and racing thoughts (n=6). The mean time since reported onset of psychosis was 5

years 1 month (range = 2-8 years). Three participants reported having received other psychiatric diagnoses including depression (n=3), Post Traumatic Stress Disorder (n=1) and Borderline Personality Disorder (n=1). Three participants reported significant traumatic experiences and two reported psychotic experiences in childhood. Comorbid sleep difficulties including nightmares, sleep paralysis and sleep walking were reported by four participants. All participants had received either ACT or CBT for psychosis within NHS secondary care services.

Participants described past or current experiences of delayed sleep onset with self-reported sleep onset ranging from two o'clock to eleven o'clock in the morning. Typical daytime sleep duration during the periods being discussed ranged from around two hours to >13 hours. In the case of the participant reporting only two hours of daytime sleep, it should be noted that this was her only reported sleep period at the time. Three participants reported long-standing subjective sleep disturbance preceding their experiences of psychosis, while four reported that the onset of sleep disturbance coincided with the onset of psychosis symptoms.

The data were developed into two overarching themes. The first theme, *Trying to Look After Ourselves*, discussed relationships between experiences of sleep-wake reversal and efforts to cope with mood and perceptual difficulties. People's primary intention was to maintain their safety in the face of perceived threats or otherwise reduce the degree of distress they were exposed to, and this had implications for both night-time sleep and daytime wakefulness. The second theme, *Developing Agency*, considers a change in participants' perspective on sleep from it being under the control of psychosis to being something that they could influence through their engagement in meaningful activity and routines.

Trying to Look After Ourselves

This theme describes two aspects of how sleep-wake reversal was affected by efforts to cope with symptoms of psychosis; distressing experiences such as hallucinations or perceptions of threat

were responded to with behaviours likely to delay or disrupt sleep, while sleep was seen as a means of avoiding contact with unwanted thoughts and emotions.

In the context of emotions such as fear and vulnerability, the timing and quality of participants' sleep was disturbed by efforts to maintain safety and wellbeing by remaining alert to potential threats and trying to reduce exposure to distressing experiences such as nightmares and perceptual disturbances. However, sleep could also feel preferential to being awake where it offered respite from unwanted experiences such as anxiety, low mood, paranoia and hearing voices. While participants often felt that one or the other of these relationships with sleep was a more prominent factor in their sleep difficulties, the majority of participants spoke to both sub-themes. One participant struggled to recall specific details about many aspects of their sleep difficulties, although he spoke strongly to an association between sleep and fear and vulnerability. These two influences on sleep-wake cycles have been developed as two sub-themes; *Sleep-Interfering Responses to Difficulties* and *Sleep as an Escape*. Together, these subthemes suggested that sleep and wakefulness had different functional outcomes depending on context, which contributed to the maintenance of participants' sleep-wake reversal.

Sleep-Interfering Responses to Difficulties

People discussed a range of unwanted or distressing experiences which they associated with poor night-time sleep including persecutory delusions, hallucinations, nightmares and anxiety. While heightened arousal and perceptions of threat were seen to have had a negative impact on sleep in themselves, participants' efforts to reduce or respond to these experiences were such that, intentionally or unintentionally, they likely further exacerbated or maintained difficulties with sleep.

For some, a significant reported barrier to sleep was that "there was so much fear" (Jon). Sleep was described as a "state of vulnerability" (Matthew) and associated with beliefs that participants or those around them were at risk of harm:

“I thought the house was constantly like under attack. ... I felt like if I had gone to sleep, like my whole family would be murdered” (Rob)

In this example, the anticipated consequences of falling asleep are extreme and the negative consequences of not sleeping at night would likely have seemed trivial in comparison. Rob implies that he felt a sense of responsibility to remain awake to safeguard his family, and he reported trying to maintain wakefulness by “compulsively drinking coffee”. Aversive experiences associated with going to bed or falling asleep was also responded to by strategies such as delaying taking medication “which make you sleepy ... until about one in the morning” (Sam) to put off sleep or with strategies intended to increase perceived safety:

“Anytime I wanted to close my eyes I had to like barricade my door and stuff ... because I was so paranoid ... even though I've checked the doors, I've checked it if it's stable, I've checked the windows .. I still end up rechecking it again cause I've just doubted myself that there's something's happened and I've gotta go and do it again and again” (Matthew)

Matthew describes a bedtime routine he developed to try to reduce feelings of paranoia or anxiety, however any sense of increased safety is fragile and short-lived, and he needs to repeatedly reassure himself. This cycle of checking and rechecking the safety of his room would have likely contributed to disturbed sleep by increasing activity levels at bedtime and delaying attempts to sleep.

People often associated night-time with an increased experience or awareness of unusual and unwanted perceptual experiences:

“I remember like some hallucinations and feeling things touching me getting much worse in the night that I wouldn't actually feel in the day ... y'know when it's like dark and the light's low? I felt like when the light was like on high, like bright lights

everywhere, like you see everything and it wasn't as bad. But if I turned the light to dark... I remember seeing a lot more things" (Lowri)

People felt that when it was dark their mind was more likely to “fill in the blanks” (Rob) with distressing interpretations about their environment. Behaviours such as keeping the room well-lit would likely have been reinforcing if associated with a reduction in distressing experiences, however this would have been at the cost of sleep hygiene and may have perpetuated difficulties with sleep.

Distraction was a common strategy for trying to manage difficulties such as hearing voices and racing thoughts:

“I scroll on my phone a lot nowadays which I'm not happy about at all but... I was just listening to voices for the entire time, it was not fun at all... Once I've started to get into bed... I have to go through the systems; I'm either watching something on my phone or I'm trying to find something to just distract myself... without you know thinking that I'm trying to do that” (Matthew)

Using computers and phones was discussed by four participants as a distraction from unwanted thoughts and experiences at night, while others talked about strategies such as going for walks or doing other physical tasks. These strategies were often acknowledged as being detrimental to sleep, for example due to “blue light” exposure (Steve), and they would have further increased night-time activity levels. Equally, Matthew alludes to the challenge of trying to enact these strategies without thinking about what he was trying to distract himself from. However, they were seen as a resource for coping with psychosis overall.

Although people described different experiences of psychosis symptoms which disturbed night-time sleep, a common factor was that the strategies employed to manage these experiences were often likely to increase, intentionally or not, wakefulness via increased caffeine intake, light exposure or bedtime activity.

Sleep as an Escape

This sub-theme considers how sleep could function as a means of avoiding unwanted experiences such as paranoia, anxiety and low mood. Sleeping could be a time of respite from aversive waking experiences and as such was seen as something “precious” (Lowri). When this was the case it seemed to establish both increased total sleep time and sleeping at atypical times as reinforcing.

Within certain contexts, sleep was felt to facilitate respite from distressing experiences:

“I felt like people were talking about me. I felt like my whole street knew and just like I was dead paranoid really. ... I didn’t want to get up. I’d rather be asleep ... so I wouldn’t have to deal with the way I’m feeling if I’m asleep” (Sam)

In the context of experiences such as paranoia, excessive or daytime sleep could be established as reinforcing due to it offering relief from experiences such as anxiety and paranoia. Here, daytime sleep was expressed as being an intentional act of experiential avoidance and social withdrawal, rather than a consequence of poor night-time sleep or a symptom of psychosis.

Sleep could also offer an escape from emotions such as low mood, loss and upsetting reflections on the impact of mental health difficulties:

“I was kind of sleeping a lot in the day. It felt almost like an escape from reality in my own mind... I didn’t know how to function with kind of being aware for the entire day... I was somewhat suicidal but I didn’t want to actually do it, and so it was almost like sleep was the next best thing” (Isobel)

Sleep was framed as a means of opting out of a distressing “reality” which felt emotionally overwhelming and was placed in a functional behavioural class with suicide. Other participants shared similar reflections that “I just wanted to die but I was scared as well to die” (Jon), and it seemed that sleep could be perceived to temporarily serve a similar function to suicide. Participants also spoke of having used drugs and alcohol to avoid unwanted emotions at times, and excessive daytime sleep

potentially had a degree of protective function in terms of reducing the likelihood of participants using more acutely harmful coping strategies.

The function of *Sleep as an Escape* was typically discussed in relation to daytime sleep rather than night-time sleep, and a number of possible reasons for this were articulated by participants. Firstly, for some participants their contact with reinforcing aspects of daytime sleep appeared to have initially been secondary to disturbed night-time sleep. Secondly, this function of sleep was often described in relation to thoughts about social interaction, whether these were established as aversive due to paranoia, low mood or experiences of interpersonal conflict. That daytime is when other people are most likely to be encountered perhaps established the conditions for daytime sleep in particular to be reinforcing in this regard. Finally, it may be that sleep was generally reinforcing for the respite it offered, but that at night the increased awareness or presence of hallucinations and delusions described in *Too Scared to Sleep* exerted the stronger influence on behaviour. Furthermore, where sleep was described as generally reinforcing, efforts to extend total sleep time into the day were acknowledged as having the unintended consequence that “obviously because I was sleeping during the day I then didn't sleep enough at night” (Isobel).

Developing Agency

As participants reflected on different points in time, different perspectives on sleep and key influences on sleep emerged. Participants' perspective changed from feeling that sleep was outside of their control to it feeling influenceable through changes in activity and lifestyle. This had implications for how capable, motivated and optimistic people felt about making positive changes to their sleep patterns.

At times when psychosis symptoms were more prominent for people, improvements in sleep were framed as out of reach and beyond their control. Psychosis was seen as the main controlling influence on sleep and the focus of participants' accounts at these points was often on barriers to change. Participants also reflected on how sleep quality and quantity was influenced by factors such as

occupation and daytime activity, often when talking about times when psychosis was better managed, This change in perspective was accompanied by greater confidence that positive changes in sleep patterns were possible and there was an increasing sense that participants felt they possessed the agency and capability to influence their sleep. These two perspectives have been developed as sub-themes entitled *We Had No Options* and *Lifestyle Influences on Recovery*.

We Had No Options

This sub-theme considers how participants positioned themselves verbally in relation to their sleep difficulties and psychosis. The language used to describe sleep difficulties during periods of psychosis was often rigid and absolute, indicating a belief that difficulties with sleep were insurmountable. Participants framed themselves as lacking the ability or agency to influence their sleep or framed past efforts to influence sleep as futile and ineffective.

Participants often talked about how improved sleep was not something that had felt realistic to consider:

“You can't really say to someone with psychosis like ‘you need to sort your sleep out’ because they can't sleep. Well I couldn't sleep. I couldn't sleep even if I tried to sleep, there was no way I was going to sleep. No chance.” (Jon)

Jon repeatedly emphasises how sleeping felt like an impossibility to him at the time, reinforcing the strength of his belief that sleep had been a hopeless endeavour. This framing of sleep precludes any acknowledgement that there may be exceptions to this; Jon reported around 6 hours of daytime sleep during the period he reflects on here, so sleep was possible under certain conditions. His focus is on the barriers to sleep, to the exclusion of considering factors that might be facilitating sleep at other times. There seemed to be an implication that professionals suggesting sleep as a treatment target have failed to understand the problem, although it is possible that he has had experiences of being advised to “sort your sleep out” without the support of specific or evidence-based interventions.

Sleep difficulties were framed as “something that no one can say or do anything to fix” (Lowri) and as being irreversible: “the brain locks itself into that state as if it's on nightshift permanently” (Steve). Within this context participants could feel that they had little or no choice in how they responded to internal experiences:

“Not being able to sleep cause I’m having a conversation in my head and I have to try to argue with the voices about what’s right and what’s wrong” (Matthew)

Matthew’s use of “have to” positions him as having had no choice, narrowing his perceived behavioural repertoire to behaviours with the primary intended function of eliminating or controlling unwanted mental events rather than facilitating sleep. In this case the behaviour was arguing with his voices, presumably in the hope that they would stop if he won the argument. This narrowing of perceived behavioural repertoires could also become a potential therapeutic block whereby participants ruled out or resisted suggestions from professionals that might support improvements in sleep:

“There was nothing anyone could do. Like my care-coordinator is always saying ‘try to take the tablets earlier’, but then I’d have a scenario ... where my body clock is saying you’re not ready for bed but the tablets are making me tired... so I’d just end up dead agitated” (Sam)

While his care-coordinator had identified a possible means of inducing sleepiness earlier in the night by taking his medication as prescribed, Sam pushed back against this, framing it as a hopeless task which he believed would cause additional problems for him.

Overall, participants use of language suggested an understanding that their sleep difficulties and behaviour had been primarily under the control of psychosis and that they lacked the capability to influence their sleep. An implication of this was that participants’ responses at the time had been the only options available to them. Often this understanding of sleep and related behaviours was framed in rigid and absolute terms that conflicted with participants’ descriptions of their sleep at the time.

Lifestyle Influences on Recovery

Improvements in sleep were seen as being facilitated by engagement with daytime activity such as exercise, healthy routines and occupation. These changes were related to an increased sense that improvements in sleep were achievable, a re-evaluation that typically occurred after finding that sleep difficulties persisted after symptoms of psychosis began to improve. Meaningful daytime activity was further felt to facilitate motivation to improve sleep and to increase tiredness at night. Developing an understanding that sleep difficulties could be influenced by daytime activity did not necessarily require people to have experienced significant improvements in their sleep. In some cases, this link was discussed in terms of an increased sense of capability to improve sleep even when the motivation to do so was lacking. Overall, participants suggested that changes in lifestyle were important in supporting positive changes in sleep.

When reflecting on times when experiences of psychosis were more prominent, sleep problems were seen to preclude obtaining work or engaging in other daytime activities: “I can't do anything in terms of getting a job... because I wouldn't be able to stay up for the next day of work” (Steve). However, ultimately it was often engagement with work or other daytime activity that was seen as preceding and facilitating improvements in sleep:

“I had to actually make sure I could actually stay awake throughout the work day, which, as you know, obviously I did but it was very difficult... it was just finding something that made it worth kind of addressing the issue, you know? Making sure that the pros outweigh the cons ... of not sleeping in the day” (Isobel)

Altering sleep patterns was seen as a difficult task, something that had to be “forced” (Steve), and as such was more likely to be undertaken once people had made daytime commitments. Even when participants felt capable of resolving their sleep difficulties, a lack of daytime commitments had implications for motivation:

“It goes hand in hand with me being unemployed ... it feels like something now I could probably sort out myself if I really wanted to, like getting up earlier, but it’s just I’ve got nothing to do, I’ve got nothing to do to get up for” (Sam)

In contrast to the framing of sleep as being out of reach described in *We Had No Options*, here the possibility of change is being considered and Sam positions positive change as something he feels capable of achieving. However, motivation for change remained low in the absence of any planned activity. One reason that improvements in sleep might not have been perceived as sufficiently reinforcing in isolation was that, in the absence of meaningful occupation or activity, day and night-time could seem comparable in terms of lifestyle: “I go for smokes every half hour and I spend literally all my time on the computer all night ... There’s nothing else. ... During the day I’m pretty similar to that” (Steve).

As well as work, developing supportive routines was seen as a “powerful” (Jon) means of facilitating better sleep. Despite Lowri previously saying that she had “tried everything” without success, she found that developing new routines helped improve her sleep:

When I struggle with nightmares or something I’ll bring up a hot chocolate every night ... do like a facial thing and just nice stuff like that just to try and settle ... I always put an audiobook on. I just feel like if you’re just thinking about sleeping then you won’t sleep. I think if you’re just listening to something, I do anyway, I drift off.

(Lowri)

Lowri found that behavioural changes supported better sleep, even in the face of continued nightmares that had previously been felt to make improvements in sleep both undesirable and unachievable. Here Lowri focuses on her own behaviour as it relates to sleep, conveying a sense of agency to respond differently to both her sleep problems and her own thoughts.

Another reported benefit of engaging with work or other activities during the day was increased tiredness at night: “Well, it's easy to sleep after a day of hard work. So, if you do hard work throughout the day, you'll have a good sleep” (Rob). Rob stated this in quite ‘common sense’ terms, however for others there was a sense that this was something they had learned over time:

“I found my sleep's a lot better ... if I've gone for a run or if I've played five a side or if I've erm been out with me mates doing anything really. Like, went clay pigeon shooting a few weeks ago and er it was cold and I was tired after that.” (Sam)

Rather than work, Sam discusses engagement with hobbies and social events, however, a similar relationship is perceived to exist in that lifestyle changes supported improvements in sleep rather than improvements in sleep or psychosis necessarily leading to improvements in lifestyle.

Table 1. Example extracts

| Trying to Look After Ourselves | | Developing Agency | |
|---|---|--|--|
| <i>Sleep-Interfering Responses to Symptoms</i> | <i>Sleep as an Escape</i> | <i>We Had No Options</i> | <i>Lifestyle Influences on Recovery</i> |
| I was drinking coffee all the time and that delays sleep ... I thought the house was constantly like under, under attack, like under threat ... I felt like if I had gone to sleep, like my whole family would be murdered. (Rob) | I felt like people were talking about me. I felt like my whole street knew and were, just, like I was dead paranoid really. ... I didn't want to get up. I'd rather be asleep ... so I wouldn't, y'know, so I wouldn't have to deal with the way I'm feeling if I'm asleep (Sam) | You can't really say to someone with psychosis like 'you need to sort your sleep out' because they can't sleep. Well I couldn't sleep. I couldn't sleep even if I tried to sleep there was no way I was going to sleep. No chance. (Jon) | I had to actually make sure I could actually stay awake throughout the work day, which, as you know, obviously I did but it was very difficult... it was just finding something that made it worth kind of addressing the issue, you know? Making sure that the pros outweigh the cons ... of not sleeping too much (Isobel) |
| When I'm trying to sleep I will, I'll usually just sit there and scroll cause I have to do something to distract me. I know it's artificial light which isn't good for sleeping. (Matthew) | I was kind of sleeping a lot in the day. It felt almost like an escape from reality in my own mind ... I didn't know how to function with kind of being aware for the entire day ... I was somewhat suicidal but I didn't actually want to do it, and so it was almost like sleep was the next best thing where it was just kind of like it's an escape for a little bit (Isobel) | It just felt like there was nothing anyone could do. Like my care-coordinator is always saying 'try to take the tablets earlier', but then I'd have a scenario ... where my body clock is saying you're not ready for bed but the tablets are making me tired so I'd just end up dead agitated (Sam) | I found my sleep's a lot better ... if I've gone for a run or if I've played 5 a side or if I've erm been out with me mates doing anything really. Like, went clay pigeon shooting a few weeks ago and er it was cold and I was tired after that ... I'm going to sort my C.V. out and send a couple of job applications so then obviously when I'm employed I'll be getting up earlier, I'll be leaving the house erm, and then I think that will help my sleep (Sam) |
| I'd write. Sit up and write on a laptop or something to put my mind on something else. (Jon) | I'd like I'd rather the night because there's not many people around ... I was scared to go out in the day. I didn't like have to deal with that if I was asleep (Jon). | No one can say anything or do anything to fix it. ... It's like you can't switch off, you just can't. (Lowri) | When I struggle with nightmares or something I'll bring up a hot chocolate every night ... do like a facial thing and just nice stuff like that just to try and settle, erm, do a bit of reading before bed. I always put an audiobook on. I just feel like if you're just thinking about sleeping then you won't sleep. I think if you're just listening to something, I do anyway, I drift off. (Lowri) |

| | | | |
|---|---|--|--|
| <p>I remember like some hallucinations and feeling things touching me getting much worse in the night that I wouldn't actually feel in the day ... I felt like when the light was like on high, like bright lights everywhere, like you see everything and it wasn't as bad. But if I turned the light to dark I could see a lot more shadows like going, I remember seeing a lot more things (Lowri)</p> | <p>When I'm at my worst ... like that's the time that sleep is more precious as well cos that's the time when you need the break from like being awake and like being confused or low or just, yeah just head like full of thoughts and voices and stuff (Lowri).</p> | <p>I would just have to stay up the whole night ... Not being able to sleep cause I'm having a conversation in my head and have to try to argue with voices in my head ... having to argue my point backwards, erm, happening in like the middle of the night. (Matthew)</p> | <p>I've been running recently. I got a treadmill. So I've been running and so my sleep's been better. You know, it's physical activity so my sleep depends on my lifestyle. (Rob)</p> |
| <p>I'd say that it started off quite reasonable. I mean it was just late nights because I was overworking myself to be able to try and get away from them [the voices]. (Steve)</p> | <p>Pay offs of night-time habits ... there's no one else around (Steve)</p> | <p>You're faced with the reality that, how do I put this, the brain locks itself into that state as if it's on nightshift permanently ... nothing has sort of been able to do anything good for me ... you just can't get to sleep no matter what you do. (Steve)</p> | <p>Well I've seen a perfect correlation pretty much, erm, every time I don't do art like I did yesterday I was up until 5am this morning. But otherwise if I do art then my brain is actually having a normal sleep cycle ... so I'm up between 6am and 8pm Like a normal person. And just because of the reality that I do art. (Steve)</p> |
| <p>I was taking mirtazapine and I mean it makes you sleepy ... I was taking them about one in the morning ... I used to dread going to bed... So I'd take mirtazapine at about one that makes you tired so I was in bed and I'd be waking up late afternoon. (Sam)</p> | <p>I've gained moments of respite, moments of comfort when I've been able to ((pause)) cos before that I hadn't slept in the daytime (Matthew)</p> | <p>I'm not sure if there is a process, it's just, you know, like you fall asleep when you're tired and you wake up when you're rested, you know... but when you're psychotic just, I don't know, you have this like energy. I call it like schizo energy. It's just you're full of energy so you just can't sleep. (Rob)</p> | <p>You have to accept, take responsibility and make the change you know? ... And that's what I started doing. I started eating better, I started going to places ... like just to get out and my heart was racing but it's just a rush and I was enjoying it. I was getting more social with people, my confidence was growing, and my sleep was getting better. (Jon)</p> |

Discussion

Participants described a range of contextual and behavioural factors that interacted with experiences of sleep-wake reversal and two overarching themes were developed from the data. *Trying to Look After Ourselves* and its sub-themes, *Sleep-Interfering Responses to Difficulties* and *Sleep as an Escape*, discussed how efforts to avoid or manage aversive experiences had implications for disrupted night-time sleep and prolonged daytime sleep. *Developing Agency* and its sub-themes, *We Had No Options* and *Lifestyle Influences on Recovery*, described a change in participants' narratives from believing themselves unable to influence their sleep to discussing how behavioural and lifestyle changes were considered to be an important facilitator of improved sleep as they moved forward in their recovery.

Participants spoke openly and in detail about their experiences although levels of insight varied across participants. Some made frequent and explicit links between their behaviour and contextual and behavioural factors, while others were earlier in the process of making sense of their difficulties with sleep. This broadly correlated with participants' stages of recovery with regard to psychosis.

Trying to Look After Ourselves

This theme considered ways in which participants' efforts to cope with psychosis contributed to disrupted sleep patterns. This involved behaviours such as staying awake at night to guard against threat and sleeping in the daytime to avoid feelings of low mood and paranoia or worry about social interaction. That efforts to cope can perpetuate or exacerbate suffering is a tenet of many modern psychological therapies (e.g. Hayes et al., 2012; Kennerley et al., 2017; Linehan, 1993), and there is a parallel here with the maintenance of insomnia through behaviours intended to promote sleep and increase levels of functioning (Harvey, 2002). Problems with sleep are often framed as reducing someone's ability to cope with psychosis (e.g. Waite, Evans, et al., 2016) and are associated with reduced social functioning (Blanchard et al., 2020) and increased positive symptoms of psychosis (Freeman et al., 2017; Koyanagi & Stickle, 2015; Waite et al., 2020). While the data presented here is

not in opposition with any of these findings, there is clinical utility in recognising that difficulties with sleep may be maintained by behaviours that people perceive as having a positive effect overall on their ability to cope. These findings suggest that sleep-wake reversal might be mediated to some extent by changing contingencies setting up differential reinforcers for sleep and wakefulness at different times of day.

Sleep Interfering Responses to Difficulties

The sub-theme *Sleep-Interfering Responses to Difficulties* explored how participants' responses to psychosis, heightened arousal, and sleep difficulties contributed to delayed and disrupted night-time sleep. In this sense an overarching intended function of behaviours relevant to disrupted or delayed night-time sleep appeared to be the avoidance or alleviation of distressing experiences. While participants' responses to their difficulties likely offered a degree of temporary relief from unwanted thoughts and emotions, they were not described as resulting in improved sleep or providing lasting resolution of other difficulties.

While previous research has described sleep being disturbed by voices, nightmares, anxiety and night-time hallucinations (Chiu et al., 2016; Reeve et al., 2019), any impact on sleep from the ways people seek to cope has received relatively brief attention. While sympathetic nervous system arousal is associated with disrupted sleep in itself (Dahl, 1996; Gupta & Sheridan, 2018), the broader literature on sleep and mental health difficulties has noted how behaviours such as going for walks, distracting oneself with computers or phones and increased activity levels in the evening can contribute to this disruption through reduced time in bed (Kanady et al., 2018), delayed sleep onset and poorer quality sleep (Joo et al., 2017). A number of participants also described a high caffeine intake during the evening, which would have intentionally or unintentionally, delayed and disturbed sleep (Clark & Landolt, 2017).

This theme related primarily to night-time sleep, in part because experiences such as hallucinations were felt to be worse at night. Hallucinations and negative thoughts and emotions have

previously been described as being worse at night among people with psychosis (Nayani & David, 1996) and primary insomnia (Schmidt et al., 2011), possibly due to people being more likely to be alone at night and having greater opportunity to reflect on unwanted private experiences (Nayani & David, 1996; Schmidt et al., 2011).

Although there were differences between the experiences and behavioural responses described by participants and cognitive-behavioural formulations of insomnia (e.g. Harvey, 2002), difficulties such as fear of sleep and nightmares have been found to respond to CBT-i (Freeman et al., 2017; Kanady et al., 2018; Talbot et al., 2014). As such this may be an effective intervention in the context of sleep-wake reversal and psychosis. Acceptance based approaches have also received interest in the context of psychosis recovery (e.g. O'Donoghue et al., 2018), and stand to benefit related sleep difficulties if cognitive and behavioural responses to psychosis function as a maintaining factor for sleep-wake reversal.

Sleep as an Escape

Participants spoke about sleep, particularly daytime sleep, representing a means of escaping from and coping with aversive waking experiences. This function of sleep has been noted in research into psychosis and sleep difficulties previously, (Chiu et al., 2016; Faulkner & Bee, 2017; Nayani & David, 1996; Waite, Myers, et al., 2016) although it is often included as a minor supplementary finding. Excessive daytime sleep is common among people with psychosis (Reeve et al., 2019), however within the sleep literature it is often assumed to be primarily a consequence of insufficient sleep quality or quantity, medical conditions, or medication side effects (e.g. Pérez-Carbonell et al., 2022; Slater & Steier, 2012). While participants sometimes saw medication and poor night-time sleep as relevant factors, daytime sleep was described as having appetitive qualities in itself. Napping to avoid negative mood states has been found in previous research with people with psychosis (Chiu et al., 2016), however it was interesting that in the present study there was often a social component to this function of sleep. Paranoia is commonly associated with a motivation to socially withdraw (Orth et al., 2022)

and several participants cited this as an appetitive consequence of daytime sleep. While paranoia may not predict sleep outcomes (Hennig & Lincoln, 2018), it may be that it can become a contributory factor in the maintenance of excessive daytime sleep through daytime sleep being established as reinforcing.

Daytime sleep can be seen as being placed by participants into a wider response class of behaviours that function to facilitate experiential avoidance of unwanted private experiences such as delusions, hallucinations, anxiety and low mood. Substance and alcohol misuse and suicide were given as other examples of behaviours that shared this function with sleep. Sleep has long been considered as a means of avoiding psychological suffering (e.g. Willey, 1924) and excessive daytime sleep representing a temporary alternative to suicide has been articulated by people suffering from low mood (Littlewood et al., 2016). It is possible that, at times, daytime sleep therefore had some protective functions for some participants by way of reducing the likelihood of them engaging in more acutely harmful behaviours. If this is the case, then interventions to reduce daytime sleep among people with psychosis should consider how to facilitate different ways of coping with previously avoided experiences.

Developing Agency

This theme considered how participants perspective on sleep changed from it being something that was beyond their control and influenced primarily by psychosis to something that they could influence through their own behaviour and their engagement with meaningful activity. The strength of this change in perspective varied between participants, with the degree of change broadly reflecting participants being at different points in their recovery. The Transtheoretical Model of Behaviour Change (Prochaska & DiClemente, 1986) suggests that behaviour change can be considered as occurring across six stages: precontemplation, contemplation, preparation, action, maintenance and relapse. *We Had No Options* could be considered to reflect a stage of precontemplation; participants were focused on the drawbacks and barriers to change and improved sleep was not viewed as a

possibility, or even necessarily a problem. *Lifestyle Influences on Recovery*, on the other hand, considered reflections on times when participants were considering the possibility of steps to improve sleep or had already made changes and seen positive outcomes. This sub-theme could be considered as reflections on times of preparation or action. This shift in participants' narrative often seemed to be influenced by the degree to which people felt they had effective options for managing psychosis and their engagement with meaningful daytime activity.

We Had No Options

This sub-theme considered how participants verbally related sleep-relevant behaviours to a lack of choice or agency. Participants often used rigid, absolute language to describe sleep as something they could not achieve "even if I tried" (Jon). Past research has found that the degree of distress experienced by people with psychosis may be related to perceptions of control and range of coping strategies (Nayani & David, 1996), and that people with psychosis and sleep difficulties may believe that sleep problems cannot be changed (Chiu et al., 2016). This framing of sleep as being out of reach or beyond participants' influence conflicted with broader reflections on sleep influences and with the fact that sleep was possible, albeit not at the times that people desired.

Discrepancies between the language used by participants to describe their behavioural repertoire and specific descriptions of sleep influences could be viewed as indicative of poor verbal tracking of sources of behavioural control (Barnes-Holmes et al., 2018). Poor verbal tracking may impair the ability to effectively respond to contingencies (Kissi et al., 2018) and is implicated in psychological suffering (Blackledge & Drake, 2013; Hayes et al., 2012). Participants' behaviour can be seen as being placed in hierarchical relations with psychosis; difficulties with sleep and constraints on their behaviour are attributed almost entirely to psychosis. This verbal behaviour, with sleep not being related to causal networks other than psychosis, may have provided a justification or a sense of understanding of participants' behaviour and difficulties, and perhaps reduced any confusion about how to respond to hallucinations or delusions (Barnes-Holmes et al., 2018). However, this may also

lead to narrow and inflexible repertoires of relational responding and reduced sense of agency (Hayes et al., 2012). Rigid verbal rules, for example rules regarding how people “have to” (Matthew) respond to hallucinations or delusions in certain ways, may also increase insensitivity to changes in contingencies making it less likely that coping strategies will be adapted or updated when they are no longer effective (Kissi et al., 2020). It has also been found that the strength of statements that oppose change, such as there being “no chance” of sleeping (Jon), can be predictive of poorer therapeutic outcomes (Amrhein et al., 2003), and motivation to engage with sleep interventions is likely to be lower in the context of low expectations of success.

This type of verbal behaviour may give insight into possible areas for psychological therapy to explore. Within an ACT paradigm, a focus might be on facilitating greater psychological flexibility through improved verbal tracking and connecting sleep with other causal relational networks (Hayes et al., 2012). In practical terms this might involve turning a client’s attention towards exceptions to unhelpful verbal rules or encouraging them to make verbal links between their behaviour in different contexts with the aim of facilitating more flexible responding rather than offering solutions. Considered within the Stages of Change model (Prochaska & DiClemente, 1986), participants’ focus on the drawbacks and futility of change rather than potential benefits could be seen to reflect a time of precontemplation. As such, exploring and strengthening areas of ambivalence and eliciting “change talk” through Motivational Interviewing might also have clinical utility (Miller & Rollnick, 2012).

Lifestyle Influences on Recovery

Meaningful daytime activity was discussed by participants as being a facilitator, rather than just a consequence, of improved sleep. People felt that the absence of meaningful daytime activity reduced their motivation to improve sleep, even when they felt they were capable of doing so. On the other hand, the presence of daytime commitments or routines was related to increased motivation to improve sleep, tiredness at night and self-efficacy and often had the effect of increasing social engagement.

The importance of engagement in meaningful activity for improving sleep is a strong theme in the wider literature on recovery and Serious Mental Illness (Andresen et al., 2003; Hendryx et al., 2009; Kerman et al., 2019; Sells et al., 2006), and work activity has been found to be associated with reduced risk of daytime sleepiness and fatigue (Theorell-Haglöw et al., 2006) and also a reduction in hallucinations (Delespaul et al., 2002). Engagement with social support is associated with improved problem, rather than emotion, focussed coping among people with psychosis and greater self-efficacy is likewise associated with more effective coping (MacDonald et al., 1998). Another factor cited by participants, consistent with broader research on sleep disorders (Lowe et al., 2019; Sherrill et al., 1998), was that daytime physical activity increased tiredness at night and facilitated night-time sleep. Alleviation of boredom is itself associated with improvements in sleep quality and daytime sleepiness (Dement & Carskadon, 1982; Teoh et al., 2021), and having regular daily routines can be facilitative of improved night-time sleep (Moss et al., 2015). Overall, it seems that increasing engagement with meaningful or routine daytime activity has the potential to support recovery from sleep-wake reversal among people with psychosis via a number of mechanisms.

While sleep disturbance is associated with occupational impairment (Reynolds et al., 2017, 2023; Swanson et al., 2011), these findings suggest that lifestyle changes can have a reciprocal role in supporting improvements in sleep. Participants' accounts suggested that it had often taken time for them to recognise this, with this recognition representing a changed understanding of the factors influencing sleep to those presented in *We Had No Options*. Often this change arose when people began coping better with psychosis without experiencing improvements in sleep, a common experience among people with comorbid sleep and psychological difficulties (Belleville & Dubé-Frenette, 2014; Ohayon & Roth, 2003). However, there was evidence that links between daytime activity and occupation were beginning to be made by those who were still experiencing significant difficulties with psychosis.

Supporting people to increase engagement with activities that may facilitate improvements in sleep might usefully draw on ACT principles of clarifying values to guide engagement in daytime activity (Hayes et al., 2012). Modular CBT programmes that include both sleep intervention and a focus on re-engaging with valued activities also appear to be efficacious (Freeman et al., 2021). Regardless of therapeutic approach, it is important to note that for daytime activity to be maintained and improve quality of life it should feel meaningful and relevant to an individual (Lim et al., 2007).

Overall, participants' responses to sleep-wake reversal and psychosis can be interpreted as being linked to their attempts to cope. As such, views on whether sleep-wake disturbances were problematic for an individual at a given time depended on the context in which they occurred. Although it would not be appropriate to infer causal relationships from this research, a perceived lack of control or choice over how to respond to difficulties may have increased likelihood of participants' using experientially avoidant coping strategies that maintained sleep-wake reversal. On the other hand, engagement in meaningful activity was viewed as a moderator of difficulties with sleep-wake periods and a facilitator of recovery. Participant's descriptions of their difficulties and behaviour also suggested a number of deviations from typical insomnia symptoms. Although psychological interventions for insomnia can be effective in the context of hallucinations and delusions (e.g. Freeman et al., 2017), robust assessment of the functional impact of sleep behaviours in context may further improve outcomes for these individuals.

Limitations

This study included data from five individuals which represents a small sample for a TA project (Braun & Clarke, 2013). However, suggestions for sample size in qualitative research vary widely, smaller samples retain the ability to generate sufficient data for complex and meaningful analysis (Braun & Clarke, 2016), and TA has even been used in case study research (Cedervall & Åberg, 2010). A smaller sample had an unintended benefit in allowing a more idiographic focus on the context from participants difficulties arose.

Participants were not formally screened for severity or nature of sleep disturbance, and from a diagnostic perspective some participants' sleep disturbance may better align with disorders such as insomnia. However, sleep disorders are often not assessed in the context of psychosis (Reeve et al., 2019) and diagnostically driven inclusion criteria may have excluded participants who are nonetheless considered by both themselves and treating clinicians to experience sleep-wake reversal. To reflect the experiences of those who are regarded in practice as experiencing sleep-wake reversal a pragmatic definition of sleep-wake reversal was adopted based on self- and clinician reports. Nonetheless, the views of people who reject or do not associate themselves with either "psychosis" or "sleep-wake reversal" may not have been captured, nor were views from individuals not currently engaged with NHS secondary care services.

All participants had received or were receiving either CBT or ACT. This may have biased participants' accounts towards making sense of sleep disorders within the context of these models and suppressed alternative perspectives. The inclusion of participants at different points in treatment and recovery and with varied levels of insight aimed to mitigate against this and showed that participants at different points of recovery reported similar intended functions of sleep-related behaviours.

Implications for Practice and Research

Participant priorities regarding treatment outcomes showed important differences to those typically seen in primary insomnia. However, current treatments available for sleep problems in the context of psychosis have primarily been developed for people with non-comorbid insomnia (e.g. Freeman et al., 2017). Although these treatments have demonstrated positive outcomes for a range of sleep experiences in the context of psychosis, the development of treatments for comorbid sleep-wake reversal and psychosis should consider potential negatively reinforcing aspects of both daytime sleep and avoidance of sleep. A particular focus for this group should be facilitating engagement in meaningful daytime activity to establish reinforcers for improved sleep.

This study highlights how topographically similar sleep behaviours can serve a different functions depending on context. This underscores the need for robust clinical assessment of sleep behaviours in the context of psychosis. Additionally, screening tools for sleep disorders may lack validity in specialist mental health settings (Faulkner & Bee, 2016) and screening and outcome measures (e.g. Bothelius et al., 2015; Buysse et al., 1989; Morin et al., 2007) do not reflect many of the experiences and difficulties reported by participants. This agrees with previous calls for the development or adaptation of sleep measures adapted for use in the context of psychosis (Faulkner & Bee, 2016).

This study did not formally assess for the presence of sleep disorders and not all participants included as having experienced sleep-wake reversal would necessarily meet diagnostic criteria for a circadian rhythm disorder. Extending the present research to explore functions of sleep behaviours among individuals with a confirmed diagnosis of circadian rhythm disorder would further contribute to understanding the development and maintenance of sleep disturbance in this subset of people with psychosis.

Conclusion

This study adopted a Functional Contextualist perspective to explore factors relevant to participants' experiences of sleep-wake reversal. This extends previous literature by providing a detailed account of these factors and identifying possible considerations for clinical practice. Participants described a complex relationship with sleep and sleep-related behaviour, which could serve multiple functions. Behavioural responses intended to support coping with delusions and hallucinations were described which could, intentionally or unintentionally, delay or disrupt night-time sleep. Sleep was also experienced as a means of escaping experiences such as paranoia and negative emotions, which served as a reinforcer of increased daytime sleep. These behaviours appeared to be maintained in part by participants feeling that they lacked other options for responding to their difficulties.

Both disruption of night-time sleep and excessive daytime sleep can be interpreted in terms of experiential avoidance, while meaningful daytime activity was viewed by participants as facilitative of recovery. The timing and content of interventions for sleep-wake reversal in the context of psychosis should be considered within the wider context of someone's life and should facilitate engagement with meaningful activity and relationships. Overall, these findings highlight that effective intervention for sleep-wake reversal and psychosis may benefit from ongoing exploration of the function of an individual's sleep behaviours in the specific contexts within which they occur.

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Contributions to Theory and Clinical Practice

This thesis includes an empirical study considering sleep-wake reversal and psychosis from a Functional Contextualist perspective and a systematic review of the literature regarding moderators of rule-based insensitivity, a theoretical principle associated with psychological suffering within in Relational Frame Theory. This chapter discusses clinical, theoretical and research implications of findings.

Systematic Review

Rule-based insensitivity refers to the effect by which verbal rules reduce sensitivity to changes in direct contingencies. Within Relational Frame Theory, rule-based insensitivity is thought to be an important underlying process in the development and maintenance of psychological suffering (Hayes et al., 2001, 2012). Psychological suffering is conceptualised within Relational Frame Theory as the adherence to rules that reduce a persons' capacity to respond effectively to contingencies in their environment (Blackledge & Drake, 2013). This thinking informed aspects of the development of Acceptance and Commitment Therapy (ACT). For example, the core process of “defusion” from literal verbal content represents the development of applied strategies to reduce the influence of unhelpful rule-governed behaviour. However, despite strong evidence for the clinical effectiveness of ACT (Arch et al., 2012; A-Tjak et al., 2015; Bach et al., 2012; Bai et al., 2020; Byrne et al., 2019; Wakefield et al., 2018) it is important to not lose sight of the importance of theoretical development (David & Montgomery, 2011; Herbert et al., 2013).

Rule-based insensitivity has been demonstrated in previous empirical research (see Kissi et al., 2020 for a review), however the evidence for factors which influence the size of this effect has not previously been reviewed systematically. While demonstrating that core theoretical principles can be observed empirically lends support to RFT, understanding how they are influenced stands to both

inform further theory development and strengthen the link between research and applied settings. Therefore, this review sought to identify factors that influence the rule-based insensitivity effect.

Implications for Future Research and Theory Development

Despite the theoretical importance of rule-based insensitivity within Relational Frame Theory, this review highlighted the dearth of empirical evidence considering the factors that may moderate this effect. A strength of Relational Frame Theory is that it is based on empirically testable hypotheses (Hayes et al., 2012) so this serves as a call for high quality studies exploring its underlying principles.

Preliminary evidence was found to suggest that rule-based insensitivity is moderated by relational coherence, relational derivation and whether a rule specifies a social or environmental contingency. The quality of the evidence was such that we have low confidence in the extent to which findings are representative of the true effects. This does however lend preliminary support to theoretical claims of the importance of both arbitrarily applicable relational responding and the type of rule in understanding rule governed behaviour (Hayes et al., 2001, 2012; Sidman, 1994). Indeed, it is notable that where concepts from AARR were considered as moderating variables for RBI the existence of a relationship tended to be borne out. AARR has been suggested to occur across four dimensions (Barnes-Holmes et al., 2017): relational coherence, relational derivation, relational complexity, and relational flexibility. While this review identified a need for further research into coherence and derivation, research into the other proposed dimensions of AARR is an obvious next step. In terms of research into rule type as a moderating factor, further high-quality research is warranted, as is research exploring the relationship between augmenting and rule-based insensitivity.

Despite the theoretical link between psychological suffering and rule-based insensitivity we could find little empirical evidence to support this claim and what evidence was available did not allow for confident conclusions to be drawn. Given the theoretical role of rule-based insensitivity in Relational Frame Theory's account of psychological suffering, high quality studies exploring this relationship would help support and refine theoretical assumptions. Of particular interest might be the

preliminary findings that depression was associated with a reduction in rule-based insensitivity, rather than increasing it as hypothesised. Seeking to replicate and elucidate this finding in higher quality trials therefore has important theoretical implications. Studies were also identified which explored a number of other variables, but again the evidence was not of sufficient quality to allow confident conclusions to be drawn. This review therefore serves to highlight a number of areas in which higher quality studies may be fruitful in supporting the development of theory.

It was apparent from this review that researchers have employed a range of different methods and measures of rule-based insensitivity. Given the low quality of the current evidence, future researchers might focus on replicating methods and outcomes across higher quality trials to facilitate the demonstration of any reliable effects.

Implications for Clinical Practice

Given the low confidence in the evidence for moderating effects of rule-based insensitivity, firm suggestions regarding application to clinical practice are difficult to make. However, a number of preliminary suggestions can be made.

The evidence suggested the possibility that different clinical manifestations of psychological distress may have different relationships with rule-based insensitivity, although this cannot be stated with any confidence based on the current evidence. However, if this finding is borne out in higher quality research it offers potential opportunities for the development of more targeted treatment approaches. For example, if depression is characterised by a high degree of sensitivity to short-term contingencies but poorer tracking of long-term contingencies this highlights a particular process to emphasise in clinical practice.

Studies exploring pliance and tracking as moderators of rule-based insensitivity provided preliminary evidence that rules are associated with greater insensitivity to direct contingencies when they specify a social rather than environmental consequence. The focus within Acceptance and Commitment Therapy is the function, rather than content, of verbal behaviour (Harris, 2019). However,

this finding suggests that rules specifying socially mediated consequences should be of particular clinical interest. There are also clinical situations in which reducing contingency sensitivity may be beneficial. For example, in the context of acute suicidal ideation, reducing sensitivity to the antecedents for suicidal behaviour may be desirable in the short term. This is implicitly recognised within Dialectical Behavioral Therapy suicide protocols that advise clinicians to directly tell acutely suicidal clients not to act on suicidal urges (Linehan, 1993). Psychological therapy relies fundamentally on language, and as such an understanding of processes underlying verbal behaviour stands to help clinicians determine how best to leverage their verbal behaviour in the service of therapeutic change.

Empirical Study

Sleep disturbance affects a majority of people with psychosis, with a significant minority presenting with experiences of sleep-wake reversal (Reeve et al., 2019). Sleep disturbance is associated with increased positive symptoms of psychosis (Koyanagi & Stickley, 2015) and increased risk of death by suicide (Miller et al., 2019) making it a critical clinical concern. Furthermore, there is evidence to suggest that sleep has a causal role in the development and maintenance of psychosis, and treating sleep problems can reduce experiences of both hallucinations and delusions (Freeman et al., 2017). However, previous research has identified that sleep may be experienced as negatively reinforcing in some contexts for people with psychosis (Faulkner & Bee, 2017). This study sought to extend this finding in the context of sleep-wake reversal and psychosis through a thematic analysis guided by a functional contextualist interpretation of behaviour. Participants described sleep difficulties emerging from a context of social isolation, lack of occupation, and challenges to self-concept. Sleep difficulties were maintained in the context of a lack of meaningful activity and relationships. The maintenance of sleep-wake reversal was interpreted in terms of experiential avoidance of unwanted experiences associated with both sleep and daily life.

Implications for Future Research and Theory Development

These findings suggest that sleep-wake reversal in the context of psychosis can be interpreted in terms of experiential avoidance, a core intervention focus within ACT (Harris, 2019; Hayes et al., 2012). ACT can be effective in treating both psychosis (Bach et al., 2012; Wakefield et al., 2018; Yıldız, 2020) and sleep problems (Paulos-Guarnieri et al., 2022; Salari et al., 2020), however it does not appear to have been empirically tested in the context of comorbid sleep problems and psychosis. This presents a potential avenue for future research in terms of establishing the efficacy of ACT in this context.

Experiences of boredom and lack of meaningful activity were reported as an important maintaining factor for participants sleep problems. Previous research has found that boredom proneness is associated with dopamine antagonist antipsychotic use (Steele et al., 2013). Given the central role boredom had in maintaining participants' sleep difficulties even after remission of other difficulties, future research might consider whether medication use has a contributory effect in persisting difficulties with sleep-wake reversal.

While motivation to engage in sleep interventions appears to be generally high among people with psychosis (Waite et al., 2020; Waters et al., 2015), participants in the present study viewed improving their sleep as a low priority without wider contextual changes. However, motivation to engage in treatment was not explored in depth in this study. Further investigation of the factors that influence motivation for sleep treatment across different presentations of sleep disturbance comorbid with psychosis would be beneficial for future intervention development.

Implications for Clinical Practice

The role of boredom and lack of meaningful occupation in maintaining participants' sleep difficulties has important implications for clinical practice. Previous literature has identified the clinical importance of addressing boredom among people hospitalised in relation to depression, anxiety and personality disorders, however concluded that it was less of a concern in relation to diagnoses of psychosis and schizophrenia (Newell et al., 2012). However, the present research suggests that

boredom may become an important consideration once acute symptoms of psychosis are well managed. Engagement in work can have positive outcomes in relation to both symptoms of serious mental illness (Dunn et al., 2008) and in terms of overall wellbeing and functioning (Mueser et al., 1997), and appears to be a cost effective intervention when considering the overall financial burden on Health and Social Care services (Knapp et al., 2013). Other avenues towards engagement in meaningful relationships and activity may include third sector organisations. However, it is important to note that alleviating boredom is not necessarily achieved by a simple increase in activity engagement (Antoniou, 2007) and any interventions should both be meaningful to an individual and facilitate experiences of autonomy (Newell et al., 2012).

Participants described how improvements in their sleep were not experienced as reinforcing without wider contextual changes. Findings suggest that motivation to engage in sleep treatment may be low in the context of sleep wake reversal and participants' priorities diverged significantly from those typical in primary insomnia. Where there is ambivalence about improving sleep in the context of psychosis Motivational Interviewing might be a helpful adjunctive approach and can be effective in the context of substance misuse comorbid with psychosis (Barrowclough et al., 2010; Martino et al., 2002). However, participants' context was such that improved sleep was seen to increase contact with aversive experiences without necessarily providing meaningful improvements in quality of life. Modular approaches to treating psychosis (e.g. Freeman et al., 2021) might be particularly effective in such cases given the individualised integration of sleep intervention within the wider context of other difficulties associated with psychosis. Given a strong theme of experiential avoidance in participants' relationships with sleep, ACT should also be a consideration. Regardless of intervention choice, facilitating opportunities for engagement with meaningful activity should be considered critical as without this improvements in sleep may not be established or maintained.

Reflections

One of the main limitations of this project was the relatively small sample size analysed in the empirical paper, which presented challenges for a robust and interpretative analysis. At the inception of this project myself and my supervisors had a number of discussions about possible challenges that may arise, in particular the difficulties we might face when recruiting. One challenge was that we were looking to recruit within a subset of a population that can already prove hard to engage (Furimsky et al., 2008; Woodall et al., 2011). Another challenge was the practicality of arranging interviews with people who might be sleeping during typical working hours. After canvassing services that might assist with making first approaches to prospective participants, we decided that there were sufficient opportunities for recruitment to proceed. I also planned to offer interviews outside of office hours, a strategy that has proven helpful in other psychosis-related research (Izon et al., 2020). We were aware that recruitment would be our biggest challenge but felt that we had a viable project if everything went to plan. Unfortunately, the week that we got approval to begin recruitment, my wife had a serious accident and I became the primary carer for both her and our one-year-old daughter which remained the case until shortly before my viva voce examination. Aside from the additional time pressures, stress and fatigue this caused, a consequence was that interviews could now only be offered during the hours that our daughter was at nursery as my wife could not care for her independently. From discussions with clinicians who were making initial approaches to service users, this lack of flexibility resulted in more than one missed opportunity to recruit both people with current sleep difficulties and people recovering from an episode of psychosis who had other daytime commitments.

In hindsight, there are a number of steps I could have considered to aid recruitment and mitigate the risk of finding ourselves with a smaller sample than we had wanted. Firstly, whilst recruiting from local services was successful initially, the pool of prospective participants being identified was smaller than anticipated. Planning early on to recruit more widely from other health boards might have helped mitigate this risk and perhaps should have been included in proposals even if we did not expect to need

this option. It is also possible that insufficient consideration was given to how to approach and work with ‘gatekeepers’, and that considering them as an integral part of the process of knowledge generation rather than as a tool for accessing participants might have paid dividends (Crowhurst & Kennedy-Macfoy, 2013).

The inclusion and exclusion criteria for the study itself is another area that could perhaps have been structured differently. We chose to focus on a subset of people with experiences of sleep difficulty and psychosis to increase homogeneity within the sample and because we hypothesised that people with sleep-wake reversal might describe more prominent avoidance functions of sleep than people with other sleep difficulties; that this might be the case was supported by clinical experiences and observations within the research team. However, including a broader range of sleep difficulties might have increased recruitment opportunities and reduced the impact of challenges recruiting people who were sleeping during the day. That similar themes have been developed from qualitative research using broader inclusion criteria in the past suggests that this could have been a reasonable decision, although the fact that themes regarded as relatively minor in other studies were supported more strongly here suggests that there may be differences between sleep presentations that warrant more focussed consideration.

We did attempt to mitigate recruitment challenges by extending invitations to people with both current and historic experiences of sleep difficulty and psychosis. This facilitated recruitment and also meant that we had contributions from people who were able to reflect on their difficulties in hindsight as well as contemporaneously, which assisted in highlighting how relationships with sleep changed over time and context. Being able to compare reflections on contemporaneous and historic behaviour helped with interpretation of both types of account by providing insight into participants’ sense-making at different stages of recovery.

All of the above has led me to reflect on the value of contingency planning when designing and conducting research. We anticipated that the research would present challenges, and each time these

were discussed we concluded that the project remained viable. However, in retrospect it would have been helpful for me to have given more consideration to how we would proceed if circumstances changed significantly, as they subsequently did. This might have influenced decision making and led to a plan whereby we were confident that we would have ample, rather than simply sufficient, recruitment opportunities.

The choice of research question has been another point of reflection for me as this research has progressed. We wanted to maintain a focus on functional aspects of behaviour as one specific aspect of sleep difficulties, where other influences on sleep have been more heavily researched in the past. This led us to the theoretically guided research question and analysis presented here. However, one challenge with a theoretically guided analysis is that it is recognised as typically leading to an analysis that trends towards being more descriptive than interpretative (Byrne, 2022). As such we might have considered developing either a more phenomenological or interpretivist research question, or a quantitative research design with a similar focus to the present study.

The systematic review paper was an opportunity to consider the evidence linking aspects of basic theory to practice. A critique of research into cognitive and behavioural therapies has been an excessive focus on advances in technology and technique, leaving the theory that provides the guiding principles and empirical justification for the approach to stagnate (Herbert et al., 2013). This review contributes to a relatively small but active area of research exploring the underlying theory of functional contextualism and Acceptance and Commitment Therapy and seeking to further clinical practice through an understanding of *how* interventions work. Taken together with the empirical paper, this project considers the application and empirical basis for a functional contextualist approach as applied to sleep difficulties and psychosis.

One limitation of the systematic review is that as a narrative review estimates of effect size cannot be made (McKenzie & Brennan, 2022). While the data available would likely not have been suitable for a meta-analysis, another quantitative synthesis method such as pooling effect sizes may

have been possible with different criteria. It was not anticipated when planning the review that much of the data would be characterised by very small samples and a lack of statistical analysis. In hindsight, this is perhaps unsurprising as the number of observations and experimental designs typical of behavioural research has long been felt to preclude large samples and statistical analysis (e.g. Skinner, 1958). Inconsistencies within the literature on RBI (Kissi et al., 2020) may still have precluded quantitative synthesis. However, it is possible that a more stringent inclusion criteria, perhaps including criteria based on quality ratings and methods of data collection and analysis, might nonetheless have allowed for a stronger synthesis. On reflection, it is interesting to recognise that I had perhaps planned the methodology without close consideration of the research design norms within this field. This feels like an obvious consideration in hindsight, perhaps reflecting a bias in my assumptions about typical study designs.

Another challenge of a narrative synthesis is that lower quality evidence can be given undue weight, with nothing other than a brief comment on quality to distinguish it from higher quality evidence (Boutron et al., 2019). With this in mind, efforts were made to ensure that contributions to the synthesis were considered carefully with regard to the quality of evidence. Whilst this felt like the appropriate course of action within the methodology of a systematic review, it also felt unfair at times. As above, behaviourist research has a long history of research characterised by small samples, large numbers of observations and an analysis rooted in observing trends within the data. Such research has contributed significantly to our understanding of human behaviour, and I therefore felt conflicted about grading studies using such methodologies as “Very Low Quality” and giving them only very brief consideration in the synthesis and discussion. Something highlighted here for me was that quality ratings themselves have to be viewed in context and understood in terms of the assumptions they make about research. Viewed from within the framework of a systematic review, such research might be of “Very Low Quality”, however that does not necessarily mean that it does not contribute meaningfully to our knowledge of human behaviour by other metrics.

Overall, this project explores aspects of both the underlying theory and applied use of functional contextualist approaches to sleep difficulties and psychosis, contributing to the extant literature in different but complimentary ways. Changes in circumstances led to unanticipated challenges, as did aspects of the research process itself. However, from this has arisen valuable learning on how to plan and conduct research that remains robust and practicable in the face of unanticipated challenges.

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Appendices

Appendix I: Example Coded Transcript Excerpt

| Transcript | Codes | Themes |
|--|---|---|
| <p>So I er I've been getting up about eleven half eleven going to bed about eleven (.) I'm probably asleep for around about twelve hours maybe (.) just (.) it used to be I just didn't want to get up, I'd rather be asleep. But now (.) last few months I'm getting up early, a bit earlier than I was (.) erm (.) and I'm alright getting off to sleep now which is good</p> | <p>Current sleep – long duration Didn't want to get up Change in motivations? Current sleep cycle feels improved</p> | <p>Trying to Look After Ourselves: Sleep as an Escape</p> |
| <p><i>Mmm ((pause)) I wonder ((pause)) you were saying that (.) it sounds like when it was perhaps at it's (.) at its worst or previously you didn't yeah didn't want to get up (.) could you say a bit more about that</i></p> | | |
| <p>Erm ((pause)) I was just a lot worse than I am I was now (.) like I'd just be lying in bed just dead anxious but <u>dead</u> anxious (.) and I just ((pause)) wanted to sleep in later (.) so I wouldn't (.) y'know so I wouldn't have to deal with the way I'm feeling if I'm asleep</p> | <p>Extending sleep to avoid waking experience Impact of symptoms High anxiety – emphasised What was the point getting up? Didn't want to get up Don't have to deal with feelings when asleep</p> | <p>Trying to Look After Ourselves: Sleep as an Escape</p> |
| <p><i>Okay (.) and I suppose I'm just thinking from what you were saying before (.) I have (.) I'm wondering how you make sense of that kinda sense of not wanting to be up and about?</i></p> | | |
| <p>Yeah ((pause)) yeah erm (.) just felt like (.) just felt like everyone was talking about me and making assumptions about me and ((pause)) yeah so ((pause)) I'd like wake up about (.) I still do it now but ((pause)) back then I'd wake up about ten (.) or earlier and I'd just [sighs] I thought "what's th- I'd rather be asleep" (.) so I'd just go back to sleep rather than get up ((pause))</p> | <p>Everyone was talking about me Paranoid thoughts influencing sleep Paranoia an establishing operation for daytime sleep? Sleep facilitating social withdrawal Sleep facilitating avoidance of symptoms</p> | <p>Trying to Look After Ourselves: Sleep as an Escape</p> |

Appendix II: Interview Schedule

Interview Schedule

Age, info on psychosis/nature of difficulties, length of difficulties, current and past occupation, living situation, how would you describe yourself/how would a friend describe you?

- 1) You were invited to take part in this research because of your experience of reversed sleep patterns. Can you describe what this is/was like for you?
 - a) *When did this happen? Prompt to describe what sleep pattern was like and any behaviours or routines associated with going to sleep. Frequency, duration, consistency and extent of any changes to sleep patterns.*
 - b) *What was happening in your life at this time? Were there times/places/situations/external events that had a particular effect on your sleeping? Do you/did you see it as a 'problem'?*
 - c) *What was a typical day for you? To what extent were daily events enjoyable, problematic, predictable, influenceable?*
- 2) Could you describe what your sleep is/has been like at other times of your life?
- 3) How have other aspects of your life been affected by your sleep patterns?
 - a) *In what ways have different sleep patterns been helpful/less helpful or good/less good for you? What payoffs and consequences have there been from your sleep patterns? What have they meant you missed or avoided?*
 - b) *Aspects of how you feel, act, roles/tasks, health? Examples of a time when something was affected by sleep?*
- 4) Is there anything else that you think might be relevant that I haven't asked about?

Appendix III: Participant Information Sheet



PARTICIPANT INFORMATION SHEET

A STUDY OF HOW REVERSED SLEEP PATTERNS AFFECT PEOPLE WITH PSYCHOSIS.

My name is Stuart Ivory and I would like to invite you to take part in a research study into how reversed sleep patterns affect people who have had psychosis.

Joining the study is entirely up to you. Before you decide, we would like you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Discuss it with friends and relatives if you wish.

Your decision about whether to take part will not affect the care you receive in any way.

Please ask if there is anything that is not clear or if you would like more information.

If you would be interested in contributing to this research, this information sheet tells you what to expect from taking part.

If you are interested in taking part in this research, please contact Stuart Ivory at stv20scn@bangor.ac.uk

WHAT IS THE RESEARCH ABOUT AND WHO CAN TAKE PART?

People with psychosis often have different sleep patterns to other people. Changing these sleep patterns can help reduce symptoms of psychosis. Understanding how sleep affects people's lives is an important part of improving the treatments and services available to people who have psychosis.

Sleep "reversal", where people sleep mostly during the day rather than at night, affects lots of people with psychosis but not much is known about why it happens or how it affects people. By speaking with people who have had sleep reversal and psychosis, we hope to better understand how this can affect people and what makes it easier or harder to cope with any difficulties.

We would like to speak with you if you have experienced both sleep reversal and psychosis within the last 3 years. We are hoping to speak with around 15 people.

WHAT WOULD TAKING PART INVOLVE?

If you are interested in taking part, we would first arrange a short phone or video call to answer any questions you might have about the research and check that you are eligible to take part.

The study will then involve a single one-hour interview with Stuart Ivory, a Trainee Clinical Psychologist. You will be asked about your experiences of sleep and psychosis and how these have affected your life. You can choose whether to be interviewed at home, at Bangor University, or remotely by video-conferencing software.

Interviews will be audio-recorded so they can be reviewed for the research. We will make sure no one can work out who you are from the reports we write. Everyone involved in this study will keep your data safe and secure.

You will have an opportunity to comment on the findings of the research before it is finalised and will be offered a summary report of the research.

BENEFITS AND RISKS OF TAKING PART IN THIS RESEARCH.

Taking part in this research is an opportunity to help improve the understanding of how sleep and psychosis affect people.

To thank you for your contribution to this research, a £20 shopping voucher will be offered in return for attending an interview.

We don't expect there to be any significant risk to anyone taking part, but it is possible that talking about how psychosis and sleep have affected your life may be uncomfortable or upsetting. If this is the case, there will be time to discuss how the discussion has affected you. If you feel you need further support, you can contact your treating healthcare team or contact:

C.A.L.L. Mental Health Helpline for Wales: www.callhelpline.org.uk, 0800 132 737

Samaritans: www.samaritans.org, 116 123

Mind: www.mind.org.uk, 0300 123 3393

WHAT ELSE DO YOU NEED TO KNOW?

If you have any concerns or complaints about the research you can contact the research supervisor, Dr Mike Jackson at mike.jackson@bangor.ac.uk

The results of this study, including anonymous quotes from interviews, will be submitted to Bangor University to be assessed as part of a doctoral qualification. It is intended that they will also be published in scientific journals.

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. If you wish to stop being part of the study, please contact me on stv20scn@bangor.ac.uk.

If at any point you tell me that you or someone else is at risk of harm, I have a responsibility to act on that. I would do my best to explain my concerns to you before any action is taken. If this happens, I would contact your treating healthcare team or another appropriate service for them to follow up with you.

All information provided will be anonymised and held securely and confidentially by Bangor University for ten years. Your rights over your data under the General Data Protection Regulations are in the attached "How Will We Use Information About You?" document.

If during the study you lose capacity to give informed consent all identifiable data collected will be withdrawn from the study. Data which is not identifiable to the research team may be retained.

This study has been reviewed and approved by Bangor University's Research Ethics Committee (project 17211), by the Health Research Authority (project ID: 314075) and by Betsi Cadwaladr University Health Board Research and Development Team.

If you have any questions, please don't hesitate to contact the researcher, Stuart Ivory, at stv20scn@bangor.ac.uk

HOW WILL WE USE INFORMATION ABOUT YOU?

WE WILL NEED TO USE INFORMATION FROM YOU FOR THIS RESEARCH PROJECT.

This information will include your:

- Name and Contact details
- Age
- Gender
- Answers to interview questions

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results.

We will write our reports in a way that no-one can work out that you took part in the study.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to stv20scn@bangor.ac.uk
- by reading the leaflet at <http://www.hra.nhs.uk/patientdataandresearch>

Appendix IV: Consent Form

IRAS ID: 314075

Centre Number:

Study Number: 17211

Participant Identification Number for this trial:

CONSENT FORM

Title of Project: A STUDY OF HOW REVERSED SLEEP PATTERNS AFFECT PEOPLE WITH PSYCHOSIS.

Name of Researcher: Stuart Ivory

Please initial box

1. I confirm that I have read the information sheet dated 08.12.23 (version 2.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to stop being part of the study at any time, without giving any reason, and without my medical care or legal rights being affected. Any information already collected about me will be kept.
3. I agree to interviews being audio recorded.
4. I agree to being interviewed **at my home / at Bangor University premises / by video conference software** (delete as appropriate)
5. I understand that I will be offered a summary report of the research findings.
6. I agree to being contacted after my participation in the event that further information is required.
7. I agree to my data being stored securely by Bangor University for 10 years as described in the information sheet

8. I agree that any data collected may be included in anonymous form in publications and conference presentations.

9. I understand that there may be instances where during the course of the research information is revealed which means the researchers will be obliged to break confidentiality and this has been explained in more detail in the information sheet.

10. I agree to take part in the above study.

Name of Participant

Date

Signature

Name of Person
seeking consent

Date

Signature

Appendix VI: Research Protocol Reviewed by Research Ethics Committee

Qualitative Protocol

FULL/LONG TITLE OF THE STUDY

A thematic analysis of the function of sleep-wake inversion among adults with psychosis.

SHORT STUDY TITLE / ACRONYM

A study of how sleep-wake reversal affects people with psychosis

PROTOCOL VERSION NUMBER AND DATE

2.0 20 Dec 2022

RESEARCH REFERENCE NUMBERS

IRAS Number: 314075

SPONSORS Number: N/A

FUNDERS Number: N/A

This protocol has regard for the HRA guidance and order of content

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor’s SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:



Date: 20/12/22

.....

Name (please print):

Dr Huw Roberts

Position: College Manager

Chief Investigator:

Signature:

Date:

..1.../..2.../23....



..

.....

Name: (please print):

Dr Mike Jackson

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KEY STUDY CONTACTS

| | |
|--------------------------------|---|
| Chief Investigator | Dr Mike Jackson, mike.jackson@bangor.ac.uk , 01248 388365 |
| Principle Investigator | Stuart Ivory, stv20scn@bangor.ac.uk , 07799730397 |
| Study Co-ordinator | N/A |
| Sponsor | Huw Roberts, College Manager Bangor University, LL57 2DG huw.roberts@bangor.ac.uk +44 1248383136 |
| Joint-sponsor(s)/co-sponsor(s) | N/A |
| Funder(s) | N/A. Doctoral student project. |
| Key Protocol Contributors | Stuart Ivory, Trainee Clinical Psychologist, stv20scn@bangor.ac.uk , 07799730397 Dr Mike Jackson, Research Director, mike.jackson@bangor.ac.uk , 01248 388365 Dr Robin Owen, Consultant Clinical Psychologist, robin.owen2@wales.nhs.uk , 01248 363551 |
| Committees | N/A |

STUDY SUMMARY

| | |
|--|--|
| Study Title | A thematic analysis of the function of reversed sleep patterns among adults with psychosis. |
| Internal ref. no. (or short title) | 17211 |
| Study Design | Qualitative |
| Study Participants | Adults who have experienced psychosis and reversed sleep patterns in the previous 3 years |
| Planned Size of Sample (if applicable) | 10-20 |
| Follow up duration (if applicable) | N/A |
| Planned Study Period | 8 months |
| Research Question/Aim(s) | To investigate possible behavioural functions that precipitate and maintain reversed sleep patterns among adults who have experienced psychosis. |

FUNDING AND SUPPORT IN KIND

| FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study) | FINANCIAL AND NON FINANCIAL SUPPORT GIVEN |
|---|---|
| N/A | N/A |
| | |

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ROLE OF STUDY SPONSOR AND FUNDER

Doctoral Student Project

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

N/A. Doctoral student project

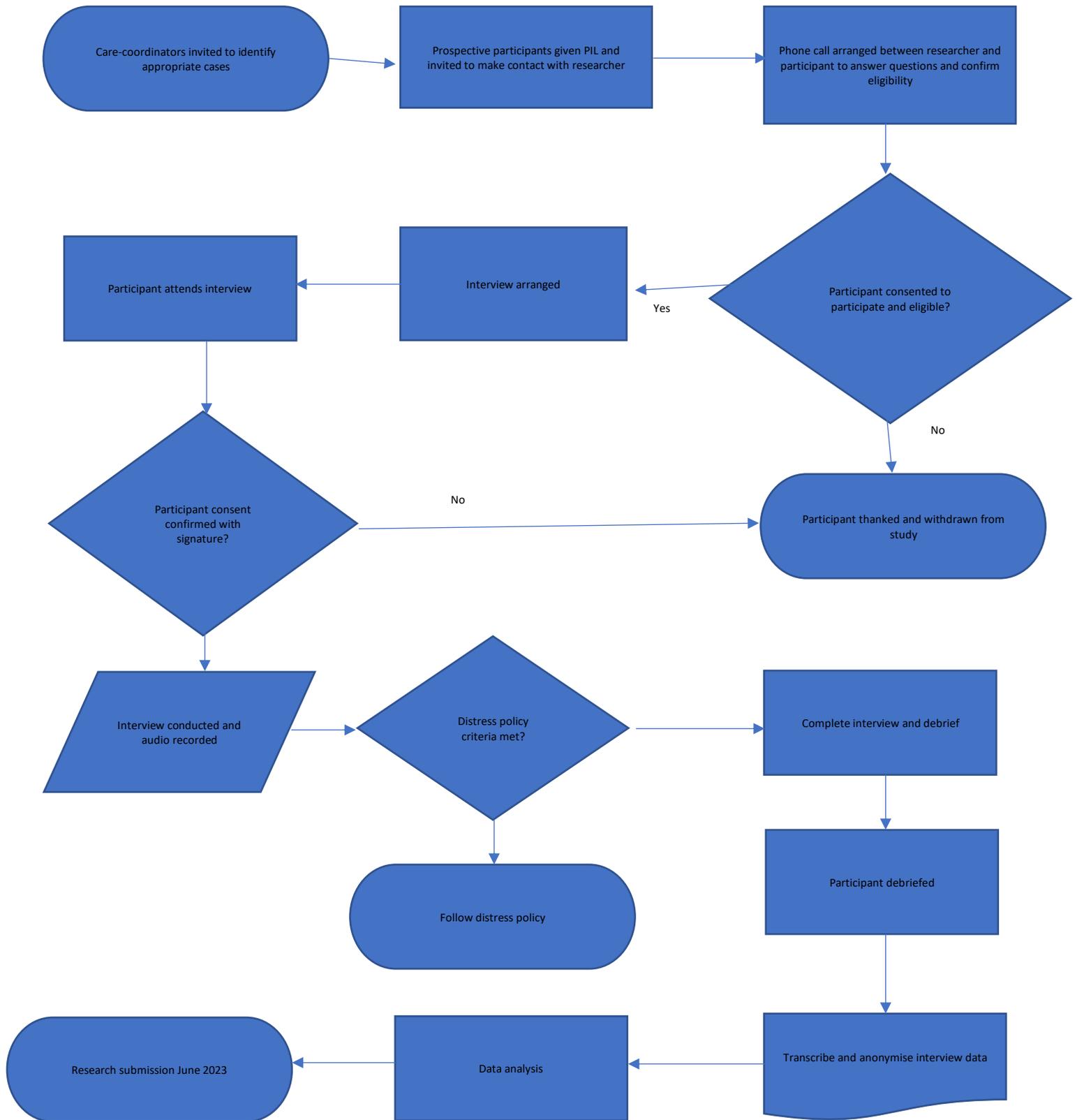
PROTOCOL CONTRIBUTORS

Stuart Ivory, Doctoral student responsible for study design, conduct, data analysis and interpretation, manuscript writing and dissemination of results. Supervised by Dr Mike Jackson and Dr Robin Owen.

KEY WORDS:

Sleep, psychosis, qualitative, sleep-wake inversion, sleep wake disorders

STUDY FLOW CHART



STUDY PROTOCOL

A thematic analysis of the function of sleep-wake inversion among adults with psychosis.

1 BACKGROUND

Sleep 'disturbance' is very common among individuals with experiences of psychosis and the degree of disturbance is strongly correlated with frequency and intensity of psychotic experiences, decreased functioning, and increased suicidal ideation and suicide attempts among people with psychosis (Chouinard et al., 2004; Miller et al., 2019; Poe et al., 2017; Wulff et al., 2012; Zaks et al., 2022). Sleep disturbance is also related to increased psychological difficulties and reduced overall functioning among individuals at clinical high risk for psychosis (Poe et al., 2017), an association that persists once mood difficulties are controlled for (Zaks et al., 2022).

Traditionally, sleep disturbance has been viewed as an intrinsic symptom of psychosis and Serious Mental Illness (e.g. Chouinard et al., 2004), however, more recently sleep has been identified as a possible causal factor in the onset and maintenance of psychosis (Freeman et al., 2017; Yates, 2016). Longitudinal research has found that sleep problems confer up to 4 times greater odds of reporting hallucinations, and that sleep problems are also related to greater odds of reporting hallucinations in the subsequent 18 months (Sheaves et al., 2016). Randomised controlled trials have shown that insomnia interventions are effective in treating both paranoia and hallucinations (Freeman et al., 2017). A systematic review by Waite et al. (2020) concluded that sleep disturbance predicted both the onset and persistence of psychosis symptoms, and that psychological interventions for sleep problems were effective in the management of both sleep problems and, to a lesser degree, psychosis symptoms. They also noted that individuals with psychosis felt that sleep was detrimental to their mental health and were motivated to engage in interventions. With sleep problems appearing to be a causal and maintaining factor for psychosis, they potentially represent a core intervention target for both individuals with psychosis and individuals at clinical high risk for psychosis. While existing interventions for sleep disorders can be implemented for these populations, it is important to understand whether any adaptations might be needed to increase their effectiveness and acceptability.

In order to effectively adapt and improve sleep interventions for these populations it would be necessary to first understand the relationship between sleep and psychosis and, in the case of psychological therapies, how people make sense of their experiences. There is some quantitative evidence that the beliefs and expectations about sleep differ between people with psychosis and individuals with sleep problems and no co-morbidities (Faulkner & Bee, 2016). There is also evidence that the relationship between sleep problems and psychosis is mediated by negative affect (Reeve et al., 2018). However, despite first line interventions for sleep being psychological in nature and previous reviews on this topic focussing on psychological frameworks (e.g. Waite et al., 2020) there is scant research exploring how people with psychosis experience and make sense of their sleep. In a qualitative investigation of sleep problems among people with psychosis Faulkner and Bee (2017) found that individuals understood sleep difficulties as being associated with a loss of normality and as loss of daytime functioning. In this sense

participants acknowledged detrimental effects of sleep difficulties and were motivated to seek intervention. However, another theme that was developed from this data was that sleep represented a survival strategy and a means of escaping from unwanted or distressing experiences. This theme was relatively underdeveloped, however there was a great deal of heterogeneity in the severity and nature of sleep problems being explored, with most participants obtaining a 'good' amount of sleep according to public health guidance. This sample heterogeneity may have obscured the extent and manner in which sleep "disorders" may function as a coping mechanism for some individuals. If there are ways in which sleep disturbance serves a useful function in people's lives, then it would be important to understand this in order to facilitate effective planning and implementing of interventions. It is also notable that while much of the literature focuses on insomnia, many people with psychosis struggle with difficulties such as hypersomnia or sleep-wake inversion (Wulff et al., 2012) which are less well understood but important to consider in the context of sleep potentially functioning as an avoidance of unwanted experiences.

As well as empirical findings, there is theoretical support for the hypothesis that some sleep "disorders" may have beneficial functions for people with psychosis. One approach that can be used to consider the role of sleep is Functional Contextualism. Functional Contextualism proposes that behaviour is best understood in terms of the functions it performs within specific present and historical contexts (Hayes et al., 2012). For example, O'Donoghue et al. (2018) proposed that delusions may function as an active avoidance of unwanted private experiences via the verbal construction of an alternate reality. They also discussed how withdrawal from daily life activities and from situations associated with psychotic experiences may function as an avoidance of unwanted experiences such as shame and anxiety. Taking a similar perspective on the onset and maintenance of sleep 'problems' gives a theoretical framework in which, in some contexts, they might function similarly as an avoidance of unwanted private experiences. This function might be anticipated to be most prominent when sleep is characterised by hypersomnia or sleep-wake reversal, both of which are common among people with psychosis (Wulff et al., 2012).

This proposed study would build on the empirical and theoretical evidence that atypical sleep patterns might have a range of functions for individuals with psychosis. Previous literature has been predominantly quantitative (see Faulkner & Bee, 2016) and focussed on problematic aspects of sleep among people with psychosis, which potentially confers only a partial understanding of the factors involved in the onset and maintenance of atypical sleep patterns in this population. Given the above problems associated with sample heterogeneity in Faulkner and Bee's (2017) study, the proposed project will use a purposive sample considering the factors associated with a narrower range of sleep patterns. Further exploring findings that sleep may function as an escape from unwanted or distressing experiences is likely facilitated by focusing on sleep patterns which reduce a person's contact with external or internal stimuli; i.e. oversleeping or sleeping during the day when social and environmental stimuli are most prominent. Oversleeping, hypersomnia, has received significant research attention in relation to other mental health difficulties such as low mood, while sleep-wake inversion is the subject of relatively little research despite a high prevalence among people with psychosis (Wulff et al., 2012) and is less well understood. As such, this research will

focus on people's experiences of behavioural functions of sleep-wake inversion in the context of psychosis.

The proposed study will involve qualitative analysis of data gathered through interviewing adults who have experienced reversed sleep patterns and psychosis within the previous 3 years. Participants will be recruited through staff in NHS mental health services.

2 RATIONALE

Psychosis is associated with high healthcare utilisation and expenditure, poor physical health outcomes (Ride et al., 2020), reduced social inclusion (Killaspy et al., 2013), and a high personal, familial and societal burden (Fusar-Poli et al., 2017). While sleep problems and psychosis have been linked, there remains a need to explore this relationship further in order to improve treatment and to understand the causes of psychosis (Freeman et al., 2017), and to understand possible helpful functions of sleep disorders (e.g. Faulkner & Bee, 2017). Much of the existing research focuses on insomnia, however people with psychosis report a range of sleep difficulties (Wulff et al., 2012) that are less well investigated.

Treatment recommendations for sleep difficulties often include behavioural interventions (e.g. American Psychiatric Association, 2022). However, the acceptability and effectiveness of these interventions will be reduced if they inadvertently reduce an individual's coping resources without supporting the development of more helpful coping strategies. As such, developing an understanding of how atypical sleep patterns function for people with psychosis supports the development of effective interventions.

The function of a behaviour, and whether it is experienced as reinforcing, is contextually bound (Hayes et al., 2012) and therefore it is to be expected that common functional outcomes vary across different sleep topographies. As such, this research aims to address gaps in the literature reviewed above whereby sleep problems are researched as either homogenous or with a focus on insomnia. A combination of empirical evidence and clinical observations of the prevalence of sleep-wake inversion among people with psychosis, combined with the dearth of literature exploring the nature of these experiences, drove the decision to focus on this here. Similar research into the function of other atypical sleep patterns would be beneficial, however including a broader range of sleep topographies in this study would be at the expense of the depth of understanding that can be generated. This research is focused on gaining an in-depth understanding about participants' experiences which has the potential to highlight aspects of sleep-wake inversion that warrant exploration both in further research and when developing formulations in clinical practice.

3 THEORETICAL FRAMEWORK

This study will employ thematic analysis techniques working from a critical-realist, contextualist, perspective. Critical realism is an ontological position which assumes that, while an objective reality exists, a researcher can only access subjective and socio-culturally bound information about it. In this sense we can only develop a partial understanding of reality. Contextualism is an epistemological position that bears some similarities to critical-realism. Contextualism views knowledge as being contextually bound and provisional and sees the validity of knowledge as being context-dependent (Braun & Clarke, 2013). Qualitative interviews give an opportunity to gather rich and nuanced data about the different functions that sleep might have for people and to explore how sleep affects their

internal cognitive and emotional experiences. It is not possible to directly observe how sleep interacts with unwanted or distressing private experiences, and so adopting a critical realist stance ensures that the research is mindful of the socio-cultural narratives that will shape the knowledge generated. Adopting a critical realist position also allows for insight to be gained into how participants make sense of their experiences, which may be relevant to increasing the acceptability of interventions and services.

Taking a contextualist stance acknowledges that there is likely to be no single “truth” about how atypical sleep patterns affect people’s lives. This is reflected in the use of idiosyncratic formulations to guide psychological intervention in relation to both sleep problems and mental ill health. Taking a contextualist stance in this research facilitates a deep exploration of participants experiences, generating knowledge that can help give direction to clinical practice and research, while privileging the diversity of experiences that participants will have had.

4 RESEARCH QUESTION/AIM(S)

Does sleep-wake inversion have beneficial behavioural functions for people with psychosis?

4.1 Objectives

To understand how sleep wake inversion functions in the lives of people with psychosis.

4.2 Outcome

To develop a coherent account of the behavioural functions of sleep wake inversion in the context of psychosis.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS

Data collection will be through detailed semi-structured interviews conducted by the primary investigator, a Trainee Clinical Psychologist. A draft interview schedule has been developed drawing on functional analysis principles and the Functional Assessment Interview. This draft interview will be discussed with experts by experience through the North Wales Clinical Psychology Programme’s People Panel.

Interviewees will have the option of being interviewed in-person or via video call. In person interviews will be conducted either at Bangor University or at the interviewee’s home, depending on their preference.

Interviews will be recorded on a dictaphone. Within 24 hours of the interview recordings will be transferred to the Stuart Ivory’s university controlled Microsoft OneDrive folder. The OneDrive account is password protected with 2-factor authentication enabled. Following upload to OneDrive the dictaphone copy will be permanently deleted. Interview data will be transcribed verbatim by Stuart Ivory as soon as reasonably practicable following the interview. As part of the transcription process, data will be anonymised by way of changing all names or other identifying information. Following transcription, the audio recording will be permanently deleted. Transcript and other data will be stored securely in the above mentioned OneDrive account. In line with Bangor University data protection policy, anonymised Data will be securely retained by the university for 10 years following ratification of the principal investigator’s DClInPsy award and will then be deleted

permanently. Any transfer of data to Dr Mike Jackson or Dr Robin Owen during the course of the study will be through granting permissions to view data within OneDrive.

Data will be analysed by Stuart Ivory, Principal Researcher, using Thematic Analysis guided by Braun and Clarke's (2006) 6-stage process of:

- Immersion and familiarisation with data
- Generating initial codes across the data set using "complete coding" whereby transcripts are systematically worked through to identify and code any content of potential relevance to the research question
- Searching for themes within the codes
- Reviewing and refining themes with the aid of techniques such as thematic maps.
- Defining and naming final themes
- Write up of the analysis.

NVivo software will be used to assist the process of coding data and developing themes. Use of this software, and any files generated, will be on Bangor University controlled servers and password protected OneDrive accounts with 2-Factor Authentication.

6 STUDY SETTING

Participant identification will take place at local NHS mental health services, with care-coordinators being asked to identify eligible participants, offer them information sheets on the study, and/or refer them to the study. The sites used for this will be those likely to have clients with experiences of psychosis and sleep wake inversion, e.g. Early Intervention in Psychosis Teams, Community Psychiatric Rehabilitation Teams, Community Mental Health Teams. This is a single centre study being carried out within Betsi Cadwaladr University Health Board.

Accessing participants for data collection will take place either at Bangor University premises, participant home address, or via video call. Venue choice will be guided by participant preference. Options for interview location will be offered to account for potential variability in participant's housing arrangements, transport access and technology/internet access.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion criteria

- Adult (18+)
- Experiences of psychosis within the last 3 years as determined by care coordinator
- Experiences of sleep-wake inversion within the last 3 years
- Has mental capacity to consent to participation, as assessed by care-coordinator
- Is presently living in community

7.1.2 Exclusion criteria

Outside of stated age range

Has not had experiences of sleep-wake inversion or psychosis within the past 3 years

Lacks mental capacity to consent to participant in research, as assessed by care-coordinator

Currently in in-patient mental healthcare service

Experiences of psychosis and/or sleep-wake inversion are secondary to physical health presentation e.g. brain injury or neurodegenerative disease.

7.2 Sampling

7.2.1 Size of sample

A sample size of 10-20 participants will be aimed for. Although it is challenging to determine how much data is required to analyse a topic, this is in line with similar research (e.g. Faulkner & Bee, 2017). 10-20 in-depth interviews should offer a rich data set for analysis without precluding deep engagement with the data.

Appropriate sample sizes in qualitative research are reflective of the scope of the research and the nature of data collection methods (Morse, 2000). Considering the relatively narrow scope of the topic under investigation and the use of in-depth interviews and purposive sampling, 10-20 in-depth interviews offers a credible opportunity to develop an understanding of the functions of sleep-wake inversion for people with psychosis.

7.2.2 Sampling technique

Sampling will be purposive, convenience/volunteer-based sampling. Potential participants who potentially meet the inclusion criteria will be identified by care-coordinators in local NHS mental health teams and asked to volunteer to participate if they are interested in doing so. As such the sample will be derived from the caseloads of NHS care-coordinators working in NHS community mental health services.

Purposive sampling is typical in qualitative research as it supports the generation of data that offers in-depth insight into a topic of interest (Braun & Clarke, 2013). In this case, sampling by asking care-coordinators to consider who on their caseload potentially meets inclusion criteria has two primary benefits. Firstly, it facilitates recruitment of people who have personal experiences of relevance to the research. Secondly, given that people with severe and enduring mental health difficulties can fluctuate in terms of their capacity to give informed consent, it offers a safeguard against recruiting individuals who have been assessed as currently lacking mental capacity.

A convenience/volunteer sampling approach has been chosen because the experiences being investigated are specific and relatively uncommon among both the general population and among populations of mental health service users. As such, recruiting from participants who are accessible to the researchers is pragmatic in this instance. Snowball sampling would potentially lead to difficulty recruiting sufficient participants as people's mental health history and sleep topography are not necessarily known to their peers, and nor are experiences of psychosis and sleep-wake inversion something that participants will necessarily share with others in their social network. Methods such as stratified sampling, while helpful in increasing sample diversity, are again limiting in this instance as the potential pool of participants is not likely large enough to be able to effectively sample across a range of demographic characteristics. Overall, the limitations of a self-selected volunteer sample are deemed here to be outweighed by the potential recruitment challenges posed by an often hard to engage population (Lal & Malla, 2015), particularly given the dearth of existing research on this topic.

7.3 Recruitment

7.3.1 Sample identification

NHS care-coordinators working in local mental health services will be provided with study details, information sheets, and inclusion/exclusion criteria for the research. They will be asked to pass on details of the study and contact details of the researcher to any clients who they believe might meet the criteria for participation in the research. Eligibility for participation in the research will then be confirmed through a phone call between the researcher and prospective participants. The final decision on eligibility for participation will be made by researchers.

Participants will be identified through Patient Identification Centres, for example NHS Early Intervention in Psychosis Services, Community Mental Health Teams, and Psychiatric Community Rehabilitation Services

Only members of a patient's existing clinical care team will have access to patient records in order to identify potential participants, check whether they meet inclusion criteria, and make an initial approach to patients. Identifiable personal information will only be available to the research team with explicit consent from the prospective participant.

Participants will be offered a shopping voucher to the value of £20 as an expression of thanks for their participation in the research.

7.3.2 Consent

The process of obtaining informed consent will be:

- Care-coordinator at PIC provides prospective participant with initial information about the study, participant information sheet, and invites them to contact the researcher.
- A telephone call is arranged between prospective participant and researcher to discuss the nature, objectives and risks of the research and to confirm eligibility. The prospective participant will have opportunity to ask any questions they wish about the research. If the prospective participant wishes to proceed and is eligible, an interview date and location is agreed.
- Prior to interview commencing the prospective participant is offered another copy of the participant information sheet and another opportunity to read and discuss it and to ask any questions. Once any questions have been asked and answered the participant will be asked to sign (or otherwise explicitly confirm consent via email if a remote interview) the consent form.
- Participants will be made explicitly aware that consent and participation in the research are optional, withdrawable, and will not in any way affect any care they receive through their healthcare team.
- Capacity to consent will be primarily assessed by the prospective participants care-coordinator. However, if at any point the researcher has reason to believe a prospective participant is not presently capable of giving informed consent any research activities relating to that person will cease and their care team will be contacted to inform them of the concerns. Wherever possible the prospective participant will be informed before any contact is made with their care team.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

Risks associated with lone working: the researcher will be conducting interviews alone and away from university or health board premises. This has associated risks including increased risk of violence or aggression towards the researcher, risk of robbery from vehicle or person while travelling to interview locations, and risk of accusations made towards the researcher. All interviews will be conducted in line with Bangor University and Betsi Cadwaladr University Health Board lone working policies which will include using a “buddy” system, carrying a mobile phone, parking and walking in well-lit areas, and arranging interviews in rooms close to frequently used corridors. The researcher has completed NHS mandatory training in managing violence and aggression.

Risk of distress to participant: This research asks people to talk about topics that have potential to be upsetting to participants, i.e. participants' experiences of serious mental illness. The first mitigation against excessive distress for participants is the process of informed consent whereby participants will be able to decide whether they feel able to discuss this before they enrol in the study. During an interview, participants may indicate distress verbally, by telling the researcher that they are distressed. However, distress may also be indicated through changes to body language, non-verbal communication, or quality or quantity of verbal engagement with the interview. The researcher/interviewer is a healthcare professional currently on a Clinical Psychology Doctorate course and has training and experience delivering psychological therapies to people in significant distress. As such the interviewer is experienced in identifying signs of potential distress. At the start of interviews participants will be reminded that they can choose to pause or end the interview at any point, without having to give a reason. The following steps will be followed if a research participant indicates, or exhibits behaviour suggestive of, experiencing high levels of stress or emotional distress:

- 1) The interview will be stopped, and the interviewer will assess the participant's current cognitive and emotional state. An assessment will be made of whether the participant feels:
 - a. Able to continue with the interview after a break
 - b. Able to go about their day
 - c. Able to keep themselves safe
- 2) If the participant wishes to continue with the interview they will be offered a break before doing so. They will be reminded that they can stop at any time and encouraged to make it known if they are experiencing high levels of distress. Their stress/distress levels will continue to be monitored.
- 3) If the participant feels unable to continue, or if there are concerns about their safety or wellbeing:
 - a. The interview will be discontinued and immediate emotional support offered by the interviewer
 - b. In the case of safety concerns, or if discontinuing the interview is deemed unlikely to sufficiently resolve any distress, the participant will be encouraged to contact their GP or local mental health service OR the researcher will contact a member of the treating health care team to request further advice or support. Researcher contact with health care providers will only be made with consent from the participant, unless there is reason to believe that the participant is unable to keep themselves or others safe. If contact is made with healthcare providers without participant consent the researcher will endeavour to explain to the participant that this is happening and why.
- 4) If an interview has been discontinued, participants will be followed up with a courtesy call (if participant consents).

Risk of distress to researcher: It is possible that during the course of interviews distressing information is disclosed by participants which could have an emotional or psychological impact on the researcher. The principal researcher is a healthcare professional with experience conducting interviews about distressing topics and has training in mitigating the impact of this. The researcher conducting interviews and data transcription and analysis will have regular supervision with Dr Mike Jackson and Dr Robin Owen (Clinical Psychologists) where the psychological impact of research can be discussed. The researcher will keep a reflexive journal that will help them to identify potential signs of unrecognised distress or emotional exhaustion. No more than one interview will be scheduled per day to allow time to manage any distress that arises from an interview.

If a participant discloses something that indicates that they pose a risk to others this will be reported to their treating healthcare team for them to assess and address safeguarding concerns. The researcher would endeavour to inform the participant that their healthcare team were being contacted, if this can be achieved in a safe and timely manner.

With any research that involves the gathering of identifiable data there is a risk of breaches of confidentiality. This risk will be managed as described in the sections relating to data protection. Bangor University and Betsi Cadwaladr University Health Board data protection and confidentiality policies will be adhered to at all stages of the research, as will the General Data Protection Regulation (2016),

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

A favourable opinion has been given on the study by Bangor University's Health and Behavioural Sciences REC. Before the start of the study, a favourable opinion will be sought from an NHS REC for the study protocol, informed consent forms and other relevant documents e.g. advertisements.

Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.

All correspondence with the REC will be retained.

It is the Chief Investigator's responsibility to produce the annual reports as required.

The Chief Investigator will notify the REC of the end of the study.

An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.

If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.

Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Regulatory Review & Compliance

Before any site can enrol patients into the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place. This will be obtained through the Betsi Cadwaladr University Health Board Research and Development team.

For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

Amendments

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor must submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

Amendments also need to be notified to the [national coordinating function of the UK](#) country (Wales) where the lead NHS R&D office is based and communicated to the participating organisations (R&D office and local research team departments of participating sites) to assess whether the amendment affects the NHS permission for that site. Note that some amendments that may be considered to be non-substantial for the purposes of REC still need to be notified to NHS R&D (e.g. a change to the funding arrangements).

All protocol versions will have a version number and an amendment history appended to allow tracking of amendments.

8.3 Peer review

Reviewed by the North Wales Clinical Psychology Programme research team.

8.4 Patient & Public Involvement

Participants will be invited to "member check" the analysis and provide comments on it as part of quality assurance/control of the analysis. Participants will also be invited to give verbal feedback on the research process following their interview and suggestions implemented if appropriate and possible, and in line with the process detailed for amendments.

8.5 Protocol compliance

Accidental protocol deviations can happen at any time. They will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately. The Chief Investigator and Sponsor will advise on the appropriate course of action in response to the deviation.

Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

8.6 Data protection and patient confidentiality

All investigators and study site staff must comply with the requirements of the General Data Protection Regulations (2016) with regards to the collection, storage, processing and disclosure of personal information and will uphold the core principles of the regulations.

Data will be recorded using a Dictaphone in the first instance, apart from consent documents which will be signed electronically or by hand. Following interviews, data will be kept on the researcher's person while they travel from the interview site. Data will then be transferred to a secure, locked filing cabinet until it can be scanned/uploaded to the researcher's password protected OneDrive account (managed by Bangor University in accordance with their data protection and information

governance policies.) The Dictaphone will then be formatted to remove any data from it, and paper documents will be securely destroyed via Bangor University's contracted confidential waste service.

To encourage the researcher to remain close to participant's accounts of their experiences, pseudonyms will be used rather than codes for participants. Participant names will be replaced with pseudonyms generated using an online random name generator, with nationality filter applied. Other identifying information such as locations or family details will be anonymised when data is transcribed by either omitting any specific information or by replacing information with an appropriate alternative (e.g. changing a place name to an alternative that has similar socio-cultural characteristics).

An encrypted, password protected file will be held in a separate folder in a password protected, 2 factor authentication enabled, OneDrive account linking participant details with pseudonyms for the purposes of allowing data withdrawal if requested. Only Stuart Ivory will have access to this file.

Access to data will be limited to Stuart Ivory for the purposes of analysis and interpretation. Access to the relevant anonymised OneDrive documents will be granted to Dr Mike Jackson and Dr Robin Owen as required for audit and quality control.

All data transmission will adhere to Bangor University's data protection and information governance policies and General Data Protection Regulation (2016).

Data will be stored by Bangor University for 10 years following ratification of the project as partial fulfilment of a doctoral course.

8.7 Indemnity

This study is covered by Bangor University's professional indemnity insurance providing cover up to £5,000,000 for any one claim. Indemnity cover is provided by U.M. Association Limited and the current policy is valid until 31st July 2023.

8.8 Access to the final study dataset

Only the Principal Investigator will have access to identifiable data in the form of audio recordings. Recordings will be transcribed and anonymised as soon as possible after interviews have taken place. The full anonymised dataset will be accessible to Stuart Ivory, Dr Mike Jackson (Chief Investigator) and Dr Robin Owen as required.

There are no plans to use the dataset in any further research other than that outlined in this protocol.

9 DISSEMINATION POLICY

9.1 Dissemination policy

Bangor University own all data arising from the study.

On completion of the study, the data will be analysed, and a Final Study Report prepared.

A copy of the final study report will be accessible through Bangor University's online research portal and will be published after the study is examined by viva in June 2023. The participant level dataset will not be published.

Participants will be provided with a copy of a draft analysis if they wish the opportunity to comment on it before publication. Any comments will be considered in a review of the analysis. Participants will be provided with a copy of the final study report once it has been submitted in partial fulfilment of the Principal Investigator's doctoral training, along with a lay summary of the outcomes.

The data set will be analysed as a whole, rather than separately for each interview transcript, so it will not be possible for participants to request results specific to their individual participation.

9.2 Authorship eligibility guidelines and any intended use of professional writers

Individually named authors will be named in order of the extent of their respective contributions to the project. Authorship credit will reflect meaningful contribution to the design, planning, implementation or production of research activity or reports.

There is no intention to commission or otherwise involve professional writers.

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11. APPENDICIES

11.1 Appendix 1- Required documentation

List here all the local documentation you require prior to initiating a participating site (e.g. CVs of the research team, Patient Information Sheet (PIS) on headed paper etc.).

Research team CVs

Patient information sheet

Consent form

Organisation Information Document (non-commercial studies).

11.2 Appendix 2 – Amendment History

| Amendment No. | Protocol version no. | Date issued | Author(s) of changes | Details of changes made |
|---------------|----------------------|-------------|----------------------|-------------------------|
| | | | | |

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.

