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Award date:
2022

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A systematic review and a social return on investment analysis of social prescribing for prediabetes patients in the UK.

Adam Edward Skinner, BA, MSc

Master by Research (MRes) Thesis

Bangor University School of Medical and Health Sciences

September 1st, 2022



‘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.’

Rwy’n cadarnhau fy mod yn cyflwyno’r gwaith gyda chytundeb fy Ngrichwyliwr (Goruchwylwyr)’

‘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.’

I confirm that I am submitting the work with the agreement of my supervisor(s)’

Acknowledgements

To my academic supervisors, Professor Mary Lynch, and Dr Ned Hartfiel, I wish to give you my sincerest gratitude for providing me with the opportunity to learn and better myself. I can never thank you enough.

To Professor Rhiannon Tudor Edwards, I would also like to thank you. Working in isolation is never an easy task, and your presence during this Masters has given me the extra motivational nudge I needed. I also wish to thank Bangor University's Academic Support Librarian Assistant, Yasmin Noorani for their advice and guidance throughout the course of this Masters. Never stop being the bright and happy person that you are.

To Penny Dowdney, I would like to thank you for your assistance concerning my funding, and additionally, I would also like to thank you for your kind nature. You have never failed to pick up the phone or answer an email. I couldn't ask for a more astute project manager. I would also like to thank KESS 2 West for funding my Master of Research. Without you this would not be possible for me, or for a great number of students.

To Sam Needham. I truly want to thank you, not only for your help, in providing your professional expertise as a registered Diabetes Technician, but for your friendship. You are a fantastic human being, and I am very lucky to have met you.

To my partner and best friend Mhairi. You have been a constant source of inspiration to me during this research. Without you, I would never have found the strength to press on. You are always there for me, and I for you.

Last but not least, I would like to thank my parents, for their continued support throughout this Masters. You have been there from day one, and I could never ask for better role models. I love you both so much.

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Abstract

Background: Conwy West Primary Care Cluster seeks to examine the evidence on the effectiveness of social prescribing for prediabetes patients and to determine the Social Return on Investment (SROI) of the MY LIFE programme. This programme is a priority for Conwy West Cluster due to a high number of citizens with Type 2 Diabetes or who are at risk of developing this chronic condition. In Conwy West, 60% of adults are of an unhealthy weight and 47% are not meeting physical activity guidelines. The MY LIFE programme seeks to prevent Type 2 Diabetes by referring prediabetes patients to a Diabetes Technician who provides information and advice, and signposts patients to community-based Social Prescribing (SP) activities that promote physical activity and a healthy diet.

Aim: The aim is to examine the evidence to identify if SP interventions in the UK are effective for managing prediabetes and to determine the SROI of the MY LIFE programme for preventing prediabetes in Conwy West, North Wales.

Methods: An SR was conducted to examine the evidence to identify if SP interventions in the UK are effective for the prevention of prediabetes. Using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, seven high-quality studies and three low-quality studies were selected for inclusion in the SR, and a thematic analysis of the included studies was conducted.

An SROI analysis was conducted to evaluate the MY LIFE social prescribing programme in North Wales. The SROI analysis consisted of six stages: identifying stakeholders, developing a theory of change, calculating inputs, evidencing, and valuing outcomes, establishing impact, and calculating the SROI ratio.

Results: The evidence from the SR suggested that participant enrolment onto SP programmes for prediabetes prevention resulted in improvements in cardiometabolic health, physical activity, psychological wellbeing, and weight-loss.

Results from the SROI analysis showed that the MY LIFE programme for prediabetes participants in North Wales generated SROI ratios ranging from £4.70 to £5.86 for every £1 invested for participants who experienced Diabetes Technician plus SP intervention, and

£4.23 to £6.46 for every £1 invested for participants who experienced the Diabetes Technician Only.

The results also indicated that most of the social value (between 54% and 69%) generated for MY LIFE participants could be attributed to the Diabetes Technician, who provided telephone support and motivation to participants every two weeks during the 8-week study.

Discussion:

Although the SROI ratios for the MY LIFE project are promising, there are some limitations in this study including the small sample size, lack of a control group and use of only one study site. Future research should use a larger sample size, multiple research sites with more than one Diabetes Technician and conduct a similar study during a non-COVID period.

Conducting this study during COVID may have resulted in fewer participants attending face-to-face SP interventions for prediabetes management.

Conclusion: Evidence from the SR showed that SP interventions can generate positive outcomes such as, improved cardiometabolic health, improved physical activity, improved psychological wellbeing, and reduced weight. In addition, the Diabetes Technician was key in generating positive SROI ratios for the MY LIFE programme. Further, SP programmes for prediabetes, such as KindEating, Slimming World, and the National Exercise Referral Scheme (NERS) contributed important additional social value.

Chapter 1- Introduction

1.1 Introduction and chapter overview

This chapter will provide background information on the prevalence of diabetes in the United Kingdom (UK), outlining the meaning of social prescribing (SP), including relevant UK strategies and programmes for diabetes prevention. In addition, this chapter will identify the importance of social return on investment (SROI) and its application within this thesis. Further, this chapter will discuss the aim and objectives of this thesis, why the research topic is necessary, and an outline of the thesis structure.

1.2 Background

Type 2 Diabetes Mellitus (T2DM) is considered to be a health condition, dependent on lifestyle choices relating to exercise and dietary intake. Type 1 Diabetes Mellitus however, is caused by one of two processes; the body's inability to produce sufficient levels of insulin, and/or a defect in how the body utilises insulin (Hackett et al., 2013; Diabetes UK, 2021; Larrañaga et al., 2021). T2DM occurs when the pancreas is unable to produce insulin at a rate that can mediate the higher levels of sugar entering the bloodstream. This in turn can lead to impaired insulin production and other chronic conditions, such as cardiovascular disease, chronic renal failure, hyperlipidaemia, and hypertension (Furmli et al., 2018; Wing et al., 2011; Mata-Cases et al., 2019). Those considered at a high risk of developing T2DM, include participants with blood glucose levels of 42 to 47 mmol/mol (6.0 to 6.4 mmol/L), which is referred to as impaired glucose regulation (IGR) or prediabetes (Kaur et al., 2020; NHS England, 2016; Sherwani et al., 2016). The HbA1c test is a recognised procedure to discover prediabetes by determining average plasma glucose levels between an eight- and twelve-week period, the typical lifespan of haemoglobin in the red blood cells (WHO, 2013; Marais et al., 2018).

The National Health Service (NHS) in England acknowledges the increasing number of patients suffering from prediabetic and diabetic symptoms, prioritizing the condition in the NHS long-term plan, directed at providing people with prediabetes with access to SP link workers who provide advice and guidance to reduce symptoms via non-clinical interventions. The NHS long-term plan aims to increase the number of link workers by 1,000 and increase the number of SP referrals to more than 900,000 by 2023/2024 (NHS England, 2019).

It is estimated that 4.2 million people in the UK are currently living with T2DM (Whicher, O'Neill & Holt, 2020). Research indicates that a further 13.6 million (21% of the UK's population) are considered to be at high risk of developing T2DM (Diabetes UK, 2021). Recent research indicates that T2DM has been increasing annually since prevalence was first reported on in 2012 (Diabetes, UK, 2020).

In 2016, statistics collected by the Welsh Government estimated that 7.3% of the Welsh population aged 17 and older were suffering with both type 1 and T2DM, the highest prevalence among the four nations of the UK (Welsh Government, 2016).

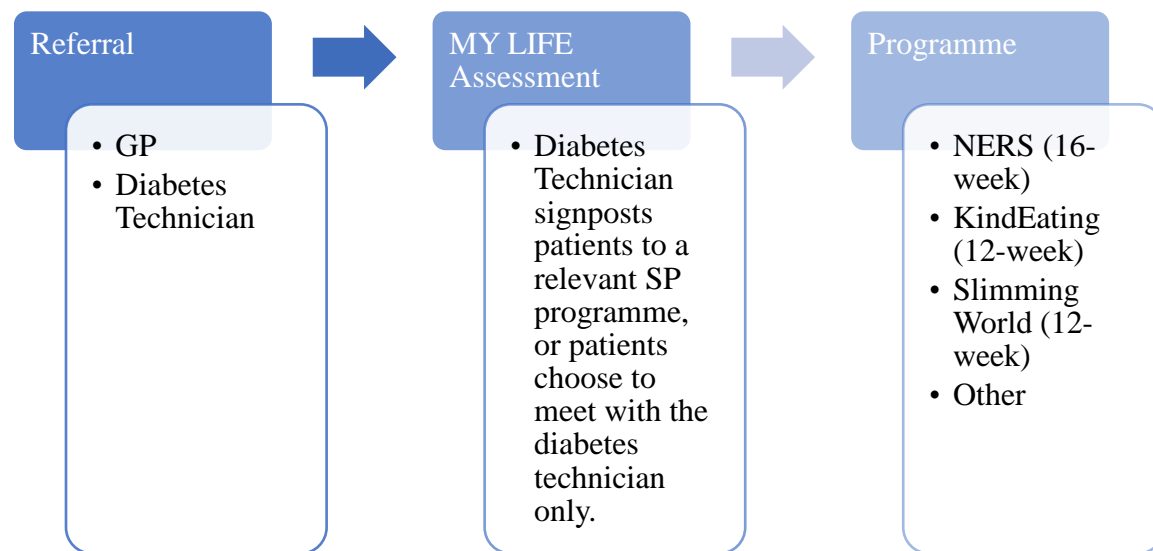
The most recent reports estimate that the NHS spends one tenth of its annual budget (£8.8billion) towards direct costs associated with T2DM, and £13.9billion on indirect costs towards indirect treatment of diabetes. Indirect costs are associated with any diabetes related work loss, increased death rates and/or informal care (unpaid care provided by a relative or non-relative) (Diabetes, UK, 2014). According to reports prior to the COVID 19 pandemic, the cost of treating diabetes in the UK had almost doubled from £650 million in 2008 to £1.1 billion in 2018/19 (Diabetes research and wellness foundation, 2019). Direct costs to the NHS for T2DM are £3,717 per person per annum (Kanavos, van den Aardweg & Schurer, 2012).

1.3 Importance of this Research

The purpose of this research was to investigate the impact of SP through 'MY LIFE', an innovative programme developed by the Conwy West Primary Care Cluster. The Conwy West Primary Care Cluster is one of the largest clusters in Wales, with 11 GP practices located across a practice population estimated at 64,000 people. The MY LIFE programme is a priority for Conwy West Primary Care Cluster after a population needs assessment undertaken in 2019 identified that 60% of adults within the cluster were considered an unhealthy weight (a BMI over 25), while 47% did not meet the physical activity guidelines. In addition, 17.6% of adults were diagnosed with hypertension and 5.6% were diagnosed with T2DM or were at high risk of developing these diseases (Conwy West Cluster, 2019). Obesity and hypertension are two lifestyle related conditions that contribute to the risk of developing T2DM, and the rationale for development of the MY LIFE programme. The programme aims to reduce obesity, prevent diabetes, promote physical activity, and improve

mental wellbeing through the implementation of SP interventions. Figure 1, illustrates a simplified outline of the care pathway process, adopted by the MY LIFE programme, followed by a detailed description of the three, main SP programmes available in Conwy (i.e., NERS, KindEating, Slimming World).

Figure 1: Referral Process to relevant SP interventions



- The National Exercise Referral Scheme (NERS) is a Wales wide programme which consists of two supervised physical activity sessions per week, lasting approximately 1-hour. This programme is delivered by an exercise professional who provides support throughout a 16-week period. The cost incurred for participants is £2 per session. Activities are chosen from a list of offers, depending on the location, and include, but are not limited to swimming, tennis, athletics, and gym. Progress reviews are provided to participants at 4-weeks follow-up and upon completion of the 16-weeks.
- KindEating is a 12-week programme funded by the NHS upon referral. KindEating is delivered by a registered dietician. Participants are provided with regular support, including weekly or fortnightly weigh-ins to measure progress during the 12-weeks. Each week of online content, offers something new to participants, including advice on healthy weight loss approaches associated to portion control, eating habits, goal setting, physical activity, meal planning, dining out, and food labels.

- Slimming World is a 12-week programme funded by the NHS upon referral. Weekly sessions are delivered by Slimming World group consultants. These sessions include weight management advice and guidance, as well as additional telephone support, buddy systems, and online support. If the health professional responsible for referral deems it necessary, a further 12-weeks of subsidised sessions can be provided.
- Diabetes Technician Only consists of participants who do not enrol onto one of the SP programmes listed but continue to receive contact from the Diabetes Technician. Participants receive advice and guidance every 2-weeks for 8-weeks from the technician concerning exercise and nutrition. Participants continue to receive suggestions from the Diabetes Technician for other programmes within their community. Participants who enrol onto SP programmes also receive the professional assistance of the Diabetes Technician.

Table 1: Diabetes Technician contact with MY LIFE participants

Baseline	<ul style="list-style-type: none"> • Participants were contacted for 30-40 minutes to complete the first questionnaire. • Participants discussed concerns involving diet, nutrition, and physical activity. • The Diabetes Technician provided a brief overview of the SP interventions available in the community.
Week 2-6	<ul style="list-style-type: none"> • Patients received follow-up phone-calls which lasted 15-20 minutes. • Diabetes Technician discussed signposting to SP interventions, and preferences. • Diabetes Technician relayed information pertaining to COVID-19 and its implications to SP programme referral wait-times. • Participants were offered advice and guidance for correct nutrition, and behaviour change techniques used to reduce unhealthy snacking. • Diabetes technician provided advice on improving snacking by replacing sugar with vegetables and whole fruits. • Advice and guidance on safely increasing physical activity through walking and bike-riding was also provided. • The technician suggested online instructional content to improve physical activity and mental wellbeing, via YouTube and an informative website known as 'Silver Cloud'.
Week 8	<ul style="list-style-type: none"> • Participants were contacted for 30-40 minutes to complete an 8-week follow-up questionnaire, to report whether improvements had been made.

1.4 Social Prescribing

SP is an important approach that offers patients a non-clinical, community-based intervention, through the help of a link worker, also known as a community navigator or health advisor (Gheera & Eaton, 2020). SP promotes a person-centred approach, offering therapeutic activities which provide a safe and engaging environment with access to mentor support, that has been shown to increase confidence and productivity (Stickley & Hui, 2012). Link workers provide the bridge between General Practitioners (GPs), patients and the community organisations delivering the SP interventions. SP interventions can include, but are not limited to, educational classes, gardening groups, cognitive behavioural therapy sessions, sports activities, and volunteering programmes (Frostick & Bertotti., 2019; Bunn et al., 2020). Such activities have shown to reduce the number of GP visits, whilst simultaneously reducing the percentage of visits to Accident and Emergency (A & E) units (Roland, Everington & Marshall, 2020; Polley et al., 2017). Based on multiple studies utilising the Warwick Edinburgh Mental Well-being Scale (SWEMWBS), patients signposted to SP programmes responded positively to interventions, reporting reduced levels of depression and anxiety due to increased social interaction and physical activity (Kilgariff-Foster & O'Cathain, 2015; Hartfiel, Gittins, & Tudor Edwards, 2020). Participants also reported improved autonomy upon engaging in activities, noting a reduction in weight, and increased physical activity (Moffatt, 2017). Physical activity, such as yoga, has also been shown to improve glycaemic control and symptoms of stress, reducing the risk of people with prediabetes from developing T2DM (Colberg et al., 2016; Innes & Selfe, 2016).

SP has also been shown to reduce prediabetic causal factors, such as reduced waist circumference and body mass index (BMI) (Deakin, Cade, Williams & Greenwood, 2006). When investigating the benefits of lifestyle interventions for the prevention of T2DM, research suggests that SP can benefit participants by improving their knowledge on nutrition and physical activity (Gillies et al., 2007).

1.5 Major UK strategies and programmes to reduce diabetes

Over the past decade, the following legislation have helped outline the importance of diabetes prevention and weight loss.

1. 2003: The '*National Service Framework for Diabetes in Wales*' was a strategy designed to tackle the rising diabetes epidemic (NHS Wales, 2003). Physical activity and weight-loss interventions were recommended to reduce the prevalence of diabetes and obesity in Wales. Although SP is not directly mentioned within the framework, the need for a strategy that implements physical activity interventions is consistent with the current aims of the 'MY LIFE' programme.
2. 2008: The UK government's '*Healthy Weight Healthy Lives*' programme, highlighted the correlation between obesity and T2DM in association with low physical activity and poor diet. The programme aims to promote healthier food choices, improved perceptions of physical activity levels and effective treatment plans for sufferers of obesity (HM Government, 2008).
3. 2009: The '*Change 4 Life Programme*' is a UK based programme which suggested a need for a proactive approach to weight-loss, providing online source material to improve autonomous, healthy decision making (NHS, 2009).
4. 2016: The '*Diabetes Delivery Plan for Wales*,' is an initiative devised by the Welsh Government to tackle the growing rate of diabetes (NHS Wales, 2016). The plan applies 'lifestyle interventions' to increase physical activity. By increasing physical activity, the NHS aims to halve the number of people with impaired glucose tolerance (IGT) (NHS Wales, 2016).
5. 2016: The NHS '*Healthier You*' diabetes prevention programme, introduced in 2016, supports a need for educating patients through interventions promoting weight-loss, improved diet and increased physical activity. This programme exemplifies the need for non-clinical-based SP interventions and supports the Betsi Cadwaladr University Health Board's 3-year plan '*Living Healthier Staying Well*'. The goal of the 3-year

plan is to identify and prevent chronic conditions through alternative pathways (NHS, 2015; Betsi Cadwaladr University Health Board, 2019).

The strategies and programmes listed above suggest that implementing non-clinically based SP interventions could improve communication between health-care professionals and patients with complications associated to obesity and T2DM in their locality. In addition, these strategies, and programmes, propose that patients would benefit from localised SP programmes. Furthermore, SP programmes could provide patients with a safe environment that provides education and facilities to promote healthy lifestyle changes (Moffatt et al., 2017; Bertotti et al., 2018).

1.6 Background to Social Return on Investment

The purpose of SROI evaluation was to compare the social value generated with the cost of providing SP interventions for the prevention of prediabetes in the UK. SROI analysis applies a similar approach to the social cost-benefit analysis framework, which compares the monetary value of inputs with outcomes (Robinson, 1993; Nicholls et al., 2012). SROI is essentially an alternative version of social cost-benefit analysis, providing greater perspective on personal and societal wellbeing. SROI places a monetary value on outcomes such as self-esteem, and optimism (New Economics Foundation, 2014).

SROI was first developed in 1996 by the Roberts Enterprise Development Fund (REDF) in the U.S.A. (REDF, 2001). Since 1996, SROI has become a more common form of methodology for evaluating interventions that generate social value. The UK Cabinet Office first developed a SROI Guide for users, which was then updated in 2012. The Guide provided a clear framework for all users looking to measure social value (UK Cabinet Office, 2012).

1.7 Research aims

The research aims and thesis contributions are included to compare the social value generated with the cost of providing SP interventions to participants of the MY LIFE programme by means of a Social Return on Investment (SROI) evaluation for the prevention of prediabetes.

The research aims and contributions of this thesis are listed as follows:

1. To conduct a Systematic Review (SR) to identify if SP interventions in the UK are effective for the prevention of prediabetes management.
2. To determine the Social Return on Investment of SP programmes for preventing prediabetes in the UK.

1.8 Thesis Contributions

This thesis:

- Provides the first Systematic Review which analyses previous research on the effectiveness of SP interventions for prediabetes patients in the UK.
- Offers the first Social Return on Investment (SROI) analysis of SP programmes for prediabetic patients in the UK.
- Generates evidence that can influence the delivery of SP interventions for prediabetes patients, not only for the Conwy West Primary Care Cluster, but also for other clusters in Wales.

1.9 Structure of Thesis

This thesis will proceed as follows:

Chapter 2 provides an overview of the methodologies used within the SR (Chapter 3) and SROI (Chapter 4), including a rationale for their inclusion within this thesis.

Chapter 3 presents an SR of the current literature undertaken to investigate the impact of SP in prediabetes management in primary care. This chapter defines the research question, outlines the process and rationale for including an SR by means of a PROSPERO protocol. This chapter identifies the study selection criteria, outlines the data extraction process, and provides an analysis and synthesis of the data from the selected studies. This chapter also identifies the key themes found from the chosen studies.

Chapter 4 presents the SROI evaluation. This chapter provides an overview of the importance of SROI, followed by the main stages of the SROI process:

1. Identifying Stakeholders
2. Developing a Theory of Change
3. Calculating Inputs
4. Evidencing and valuing outcomes
5. Establishing Impact
6. Estimating the SROI Ratio

Chapter 5 provides a discussion of the main findings of the SR and the SROI evaluation, including recommendations for future research.

1.10 Chapter Summary

This chapter provided a background on the prevalence of Type 2 Diabetes Mellitus (T2DM), and its association to diet and lifestyle. Recent costs of NHS healthcare resource use in association to T2DM were also provided. An overview of the MY LIFE programme, including a breakdown of T2DM and other chronic diseases affecting the Conwy West Primary Care Cluster were included. SP was defined and the types of SP programmes available to MY LIFE participants was provided. Furthermore, a list of major UK strategies and programmes for people with T2DM was provided. Finally, the research aim, and a list of contributions were included followed by a structural outline of this thesis.

Chapter 2 Research Methods

2.1 Introduction and Chapter overview

The purpose of this chapter is to provide an outline of the methodology for an SR and a rationale to justify its inclusion (Chapter 3), followed by an outline of the methodology for an SROI, including a rationale (Chapter 4).

2.2 Systematic Review Rationale and Methods

The first step was to organise a meeting with the Bangor University Research Librarian to seek consultation on the appropriate review method. The resulting options included a scoping review, a literature review, or a systematic review (SR). Due to the specificity of the research topic, the approach most applicable to the study was a SR. The SR is a rigorous approach that aims to answer a particular research question, adopting the population, intervention, comparator, outcome (PICO) framework to identify key research parameters (Sargeant & O'Connor, 2020; Miller & Forrest, 2001). By comparison, a scoping review is normally conducted by researchers, prior to conducting a SR, to assist with defining the main research topic. This enables a simplified research question to arise for the SR process to begin (Arksey & O'Malley, 2005).

Literature reviews, however, rely solely on information provided by the author of the study. A literature review is essentially an overview of existing papers and relies heavily on trust of the authors whose work is included (Kowalczyk & Truluck, 2013). Relying on the trustworthiness of an author's work, whilst selectively choosing papers brings a certain level of bias which SRs avoid through rigorous, analytical processes. Literature reviews are also void of any structural processes that outline the justification of included papers (Snyder, 2019).

Further, to assure that only papers of relevance and of high quality were obtained, the SR process followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) framework (Moher et al., 2009). The PRISMA framework abides by a 27-item checklist for reviewers to follow when conducting a SR. Reviewers are required to present a flow diagram of the papers initially found upon searching the chosen databases, excluding papers that do not meet the inclusion criteria found within the 27-item checklist (Panic et al., 2013). Due to the specificity of the checklist and an inability to regulate outside the list's parameters, the likelihood of bias is greatly reduced (Cook et al., 1997; Murlow, 1994). Therefore, SRs are regarded as being the standard methodological approach when informing future researchers and policy makers (Gopalakrishnan & Ganeshkumar, 2013).

A need for a rigorous approach was considered when examining the quality of the SP papers found during the SR, due to current gaps in SP literature in which many papers reported short-term follow-up intervals and missing data sets (Bickerdike et al., 2017). Current evidence suggests that methodological issues exist within the SP literature such as heterogeneity of interventions and the locations in which they are implemented. This variability leads to disputes pertaining to the standards and practice of SP (Husk et al., 2019).

However, although there are outstanding issues relating to SP data collection and study length, the short-term results reported positive outcomes for a majority of SP interventions (Woodall et al., 2018). Originally, SRs were used to synthesise papers of high quality to inform evidence-based medicine of the effectiveness of healthcare interventions (Chandler, 2013; Sha & Chung, 2009). Due to a demand for high quality reviews, SRs were adopted into public health research during the 1970's (Centre for Reviews and Dissemination, 2009). The transition into public health is what made the SR strategy applicable to this thesis on the study of prediabetes prevention.

During the screening process of the SR, it was accepted that inclusion of both observational and experimental papers was acceptable. Originally, the inclusion of only experimental papers, such as the gold standard RCT, was desirable due to the blinding and random allocation of participants (Nardini, 2014). Evidence also recognises that RCTs are the most efficient approach to answering a research question. (Edwards et al., 1998). However, it is not always possible to conduct an RCT due to the cost and time involved.

A recent Cochrane review confirmed the importance of reviewing both observational and experimental papers. However, there are some concerns regarding the accuracy of observational papers due to the risk of selection bias and/or absence of sufficient confounders (Mamdani et al., 2005). Nevertheless, observational, and experimental papers were included in this SR.

2.3 SROI Methods

The SROI framework consists of six stages:

1. Identifying Stakeholders
2. Developing a Theory of Change
3. Calculating Inputs
4. Evidencing and valuing outcomes
5. Establishing Impact
6. Estimating the SROI Ratio

2.3.1 Identifying stakeholders

The first stage of the SROI analysis involves defining the scope of the evaluation and listing the appropriate stakeholders. MY LIFE Stakeholders consisted of those who experienced change as a result of the events taking place during the intervention. (Banke-Thomas et al., 2015). In this study, the primary stakeholders included obese participants with a BMI of ≥ 30 , with a diagnosis of pre-diabetes, aged 18 years and over, situated in the Conwy West region. The NHS are also stakeholders because they provide the funding necessary to deliver the MY LIFE programme. The following inclusion criteria were included for, “MY LIFE” participants:

- Aged 18+
- BMI score of ≥ 30
- Prediabetic (as identified by practice nurses and/or Diabetes Technician)

2.3.2 Developing a theory of change

A theory of change was included to provide an outline of the processes set in place to achieve an intended outcome (Maier et al., 2015).

These processes include:

1. Inputs- which includes any costs pertaining to the delivery of the programme, such as equipment costs, staffing costs, and administrative cost.

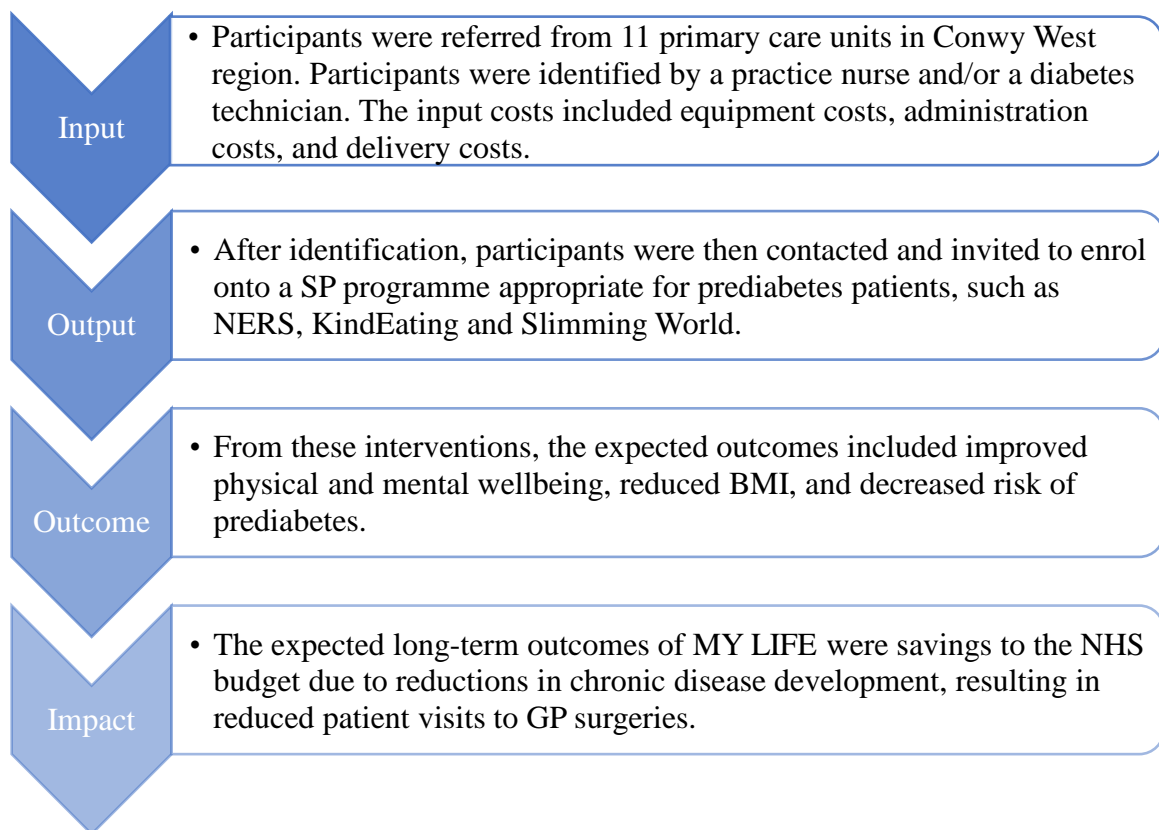
2. Outputs – includes the number of participants who experience SP interventions as a result of the input costs.
3. Outcomes - the intended outcomes relating to the SP interventions provided to MY LIFE participants, which included reduced weight, improved physical activity, increased mental wellbeing, etc.
4. Impacts- the reduced use of NHS health service resource use as a result of positive outcomes (See Figure 2).

A theory of change illustrates the intended changes of an activity or programme via narrative and visual representation (Banke-Thomas et al, 2015). Further, the theory of change pertains to the inputs an organisation implements, and the changes that take place once implemented. These changes reflect positive or negative outcomes in relation to the stakeholder, which for the context of this study, refers to the MY LIFE participants and the NHS (Lawlor & Bowen, 2016).

Working alongside stakeholders to develop a theory of change model is essential to the SROI, as this enables a person-centred approach to help establish outcomes that matter to the stakeholder. Measuring outcomes relevant to the population intended to experience positive change adds robustness to the SROI (Cabinet office, 2012).

A complete theory of change presents a clear evaluation of what stakeholders deem important, establishing not only values, but values that are important to a particular population within a programme. The MY LIFE programme made use of the theory of change model, identifying relative outcomes, providing a forecasted hypothesis of the value particular outcomes could bring to prediabetic patients of the Conwy West region. A theory of change model would also maintain transparency and consistency of the MY LIFE programme, as it is also a tool to keep the researcher and reader on track (Paina et al, 2017).

Figure 2. Theory of change overview



2.3.3 Calculating inputs

To identify input costs, researchers consulted with the Diabetes Technician, members of Public Health Wales, and Conwy County Borough Council. Total costs for MY LIFE programmes included equipment costs, staffing costs, and administrative cost. These input costs help to identify the cost to the NHS in delivering SP interventions (Nicholls et al., 2012).

2.3.4 Evidencing and valuing outcomes

Measuring outcomes

Prediabetic patients who agreed to participate in the study received a participant information sheet explaining the purpose of the study, why they had been invited, and what was involved (e.g., time commitment). Further, participants were informed that all data collected would remain anonymised and confidential. The participant information sheet stated that participation in this study was voluntary and informed participants that they may withdraw from the study at any time without giving a reason. All participants signed a consent form

before completing baseline questionnaires. Baseline and 8-week follow-up questionnaires were completed by MY LIFE participants to measure changes experienced from contact with the Diabetes Technician and from participation in SP programmes. Questionnaires measured changes in physical activity, diet, smoking, alcohol consumption, mental wellbeing, health-related quality of life and health service resource use. At 8-weeks a follow-up questionnaire was completed by participants to assess their overall experience of the MY LIFE programme. Participant questionnaires consisted of the following valid and reliable outcome measures (Table 2).

Table 2. Outcome measures

Outcome Measure	Description
SWEMWBS	SWEMWBS is a 7-item questionnaire, used to assess the mental wellbeing of members within a population (Stewart-Brown et al., 2009).
EQ5D-5L	EQ5D-5L is a 5-item questionnaire with 5 options to choose from. The five items cover: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression (Janssen et al., 2012).
Scottish Physical Activity Questionnaire (SPAQ)	The SPAQ is a questionnaire used to identify the level of physical activity in which a participant engages during the previous week (Lowther et al., 1999).

Valuing outcomes

After the quantity of change was determined, monetary values were assigned to outcomes selected from the HACT Social Value Calculator (2018) and HACT Mental Health Social Value Calculator (2018). Unit Costs of Health and Social Care, and NHS reference costs were also obtained to quantify the change in health service resource use (Jones & Burns, 2021; NHS, 2021; Fujiwara et al., 2017).

Table 3. Wellbeing Valuation Methods

Outcome	Outcome Measure	Value Set
Mental Wellbeing	SWEMWBS	Mental Health Social Value Calculator
Physical Activity	Scottish PA questionnaire	Social Value Calculator
Good Overall Health	EQ5D-5L	Social Value Calculator

HACT Social Value Calculator

Social value is the end-product generated when using the SROI evaluation framework. It involves the quantification of intangible outcomes, such as wellbeing, which are assigned a monetary value. The HACT Social Value Calculator consists of financial values for health outcomes that have been calculated using wellbeing valuation. Wellbeing valuation is based on data from large national UK datasets, including the British Household Panel Survey, which holds more than 10,000 sets of values from the same stakeholders since 1991 (Trotter et al., 2017). These datasets contain figures associated to wellbeing and life situations. These figures are robust and consistently updated within the HACT Social Value Bank.

Frequent moderate exercise and good overall health were outcomes chosen from the HACT social value bank. Outcomes were assigned social value, depending on the participant's improvements at 8-week-follow-up. These scores were calculated, and a value was awarded to participants who improved by 10% or more.

Mental Health Social Value Calculator

Wellbeing valuation can also be used to place a monetary value on outcomes collected from the SWEMWBS questionnaire (Trotter et al, 2017). To place a value on mental wellbeing, participants of the MY LIFE programme were asked questions from the SWEMWBS questionnaire at baseline and week 8. SWEMWBS scores for each participant range from a minimum of 7 to a maximum of 35 (See Figure 3).

Figure 3. SWEMWB values and how to apply them (Trotter et al., 2017).

The new SWEMWBS values and how to apply them		
As with the existing Social Value Bank, the wellbeing valuation method was used to value movements on the SWEMWBS scale. These values represent the additional money, the average individual would need to improve their wellbeing, which is the same amount as the improvement in their SWEMWBS score.		
Category	Overall SWEMWBS score	Full model value
1	7-14	£0
2	15-16	£9,639
3	17-18	£12,255
4	19-20	£17,561
5	21-22	£21,049
6	23-24	£22,944
7	25-26	£24,225
8	27-28	£24,877
9	29-30	£25,480
10	31-32	£25,856
11	33-34	£26,175
12	35	£26,793

As illustrated in Figure 3 above, the HACT Mental Health Social Value Calculator uses wellbeing valuation to generate a monetary value from SWEMWBS (Trotter et al., 2017).

There are six steps required for calculating social value using SWEMWBS, and they are implemented as follows:

1. Participants completed SWEMWBS questionnaires at baseline and follow-up periods.
2. Scores for all seven SWEMWBS questions were calculated at each interval.
3. A total score ranging from 7-35 was recorded for each participant during each interval.
4. The appropriate SWEMWBS monetary value was assigned to each participant, depending on their score.
5. The baseline value was then subtracted from the follow-up value.
6. A deadweight percentage of 27% was used to calculate the total social value for each participant to enable a total cost per person. Deadweight refers to the amount of change participants expect to experience had the MY LIFE programme not taken place (Arvidson et al., 2010).

27% is the standard percentage required to calculate deadweight using the HACT Mental Health Social Value Calculator and is recommended by the Housing and Communities Agency (Dancer, 2014; Fujiwara et al., 2017).

NHS health service resource use

NHS health service resource use was measured two months before the intervention and two months during the intervention. Participants self-reported the number of GP visits, nurse visits, outpatient visits, ambulance calls, and accident and emergency visits.

2.3.5 Establishing Impact (using the Social Value Calculator)

To reduce the likelihood of overclaiming on the value of outcomes, the SROI analysis used the HACT Social Value Calculator to calculate deadweight, displacement, and attribution. Deadweight is defined as the amount of change the participants/stakeholders would have experienced if the MY LIFE programme did not take place (Arvidson et al., 2010).

Displacement identified whether participants relinquished certain activities that were

potentially beneficial to their wellbeing in order to participate in the MY LIFE programme (Steed & Nicholles, 2011). Attribution measured the likelihood that the change occurred as a result of other organisations/activities (Solórzano-García et al., 2019). To determine the SROI ratio, deadweight, displacement, and attribution percentages were measured using questions provided to participants at the 8-week follow-up. These three measurements helped ensure accurate representation of the social value achieved (Table 4).

Table 4. Attribution, Deadweight, Displacement

Attribution:	Deadweight:	Displacement:
How much of this change is due to the MY LIFE programme?	How much of this change would have happened anyway (if you had not participated in the MY LIFE programme)?	By participating in the MY LIFE programme over the last several months, how much have you had to give up other activities that benefitted your health and wellbeing?

2.3.6 Estimating the SROI ratio

Calculating the SROI ratio required a formula comprising of the total value of outcomes experienced by the stakeholder divided by the total value of inputs invested into the MY LIFE programme. This helped to establish a SROI ratio for every £1 invested. The total social value generated per participant was compared with the total cost per participant.

2.4 Chapter Summary

This chapter identified the methodologies and rationales used to conduct a SR and a SROI evaluation for implementing SP interventions in the prevention of prediabetes for obese patients in the UK.

Chapter 3: Systematic Review

3.1 Introduction

This chapter presents an overview of the Systematic Review (SR) undertaken in this thesis to explore the peer reviewed evidence on the use of SP interventions and prediabetes management in primary care, and their effects on physical and mental wellbeing in the UK. SRs were originally implemented by members of the British Medical Journal (BMJ) and the Cochrane Centre in London in 1993 (Schulz, Chalmers, Hayes & Altman, 1995). The purpose of a SR is to answer a specific research question by sourcing relevant papers. Further, the SR incorporates an advanced search method within multiple databases, to identify both quantitative and qualitative studies (Pollock & Berge, 2018). This SR examined the steps taken to scrutinise and include eligible studies, based on a set of data extraction and quality appraisal methods. The results were synthesised and presented through a thematic analysis. The SR concluded with a discussion of the strengths and limitations of included papers, as well as suggestions for future research.

3.2 Systematic Review process

The purpose of a SR is to answer a specific research question by sourcing relevant papers, using an advanced search method within multiple databases to identify both quantitative studies in the form of Randomised Control Trials (RCT's) and qualitative studies, such as interviews and observations (Pollock & Berge, 2018). Following the implementation of a Population, Intervention, Comparator and Outcome framework (PICO), titles, abstracts and full texts were screened using reference managing software, to determine which papers met the inclusion/exclusion criteria (Lajeunesse, 2016). Upon inclusion, the papers were then assessed to determine the risk of bias and quality appraisal (Katikireddi, Egan & Petticrew, 2015; Gough, Oliver & Thomas, 2017).

3.3 Aim of Systematic Review

The aim of this SR was to investigate the available evidence on the impact of SP interventions on the preventative management of prediabetic patients in the United Kingdom (UK). Electronic databases and grey literature were searched to retrieve appropriate literature following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Moher et al., 2009). The GRADE (Grading of Recommendations, Assessment, Development and Evaluations) framework was used to assess the quality of included papers (Guyatt et al., 2011).

3.4 Literature search strategy

The protocol was registered with the University of York, SR database, PROSPERO CRD42021261710 ([Skinner, Lynch & Hartfiel, 2021](#)). The SR was registered with Prospero to help reduce potential bias, and to reduce the likelihood of duplication occurring from future research if registration was not undertaken (Stewart et al., 2012).

The patient/population, intervention, comparator, outcome or (PICO) framework, was applied to construct a clear research question associated to a health-related issue (see Appendix A) (Richardson et al., 1995). Keywords were devised and grouped within the PICO framework to increase the likelihood of finding relevant papers. The population referred to patients with prediabetes or T2DM. The intervention referred to SP interventions. No comparators were identified. The outcome referred to improvements in physical and or mental wellbeing. Medical and non-medical subject headings (MeSh) were included by searching online for reviews and clinical trials of a similar nature.

A specialist librarian was consulted on the correct use of truncation and the selecting of applicable keywords. Search terms were assembled, alongside “OR” Boolean operators within groups and with “AND” Boolean operators between groups. These search terms were included as they pertained to the research question, concerning the potential benefits of conducting a SR to deduce whether existing literature identified positive or negative outcomes for the implementation of SP for the prevention of prediabetes in obese people in the UK (Table 5).

Table 5. Systematic search strategy

Participants/Population	Intervention/Social Prescribing	Outcome
Diabet*	Social prescri*	Improved Well-being
Type 2 diabet*	Social intervention*	Improved Wellbeing
Obes*	Community-based intervention*	Physical activit*
Hypertens*	Community referral*	Mental health benefit*
Adult*	Non-medical referral*	Reduced BMI
	Community referral intervention*	Mental Wellbeing
		Mental Well-being

Please note that all search terms that include an asterisk (*) are used to truncate keywords within an advanced search.

3.4.1 Study selection criteria

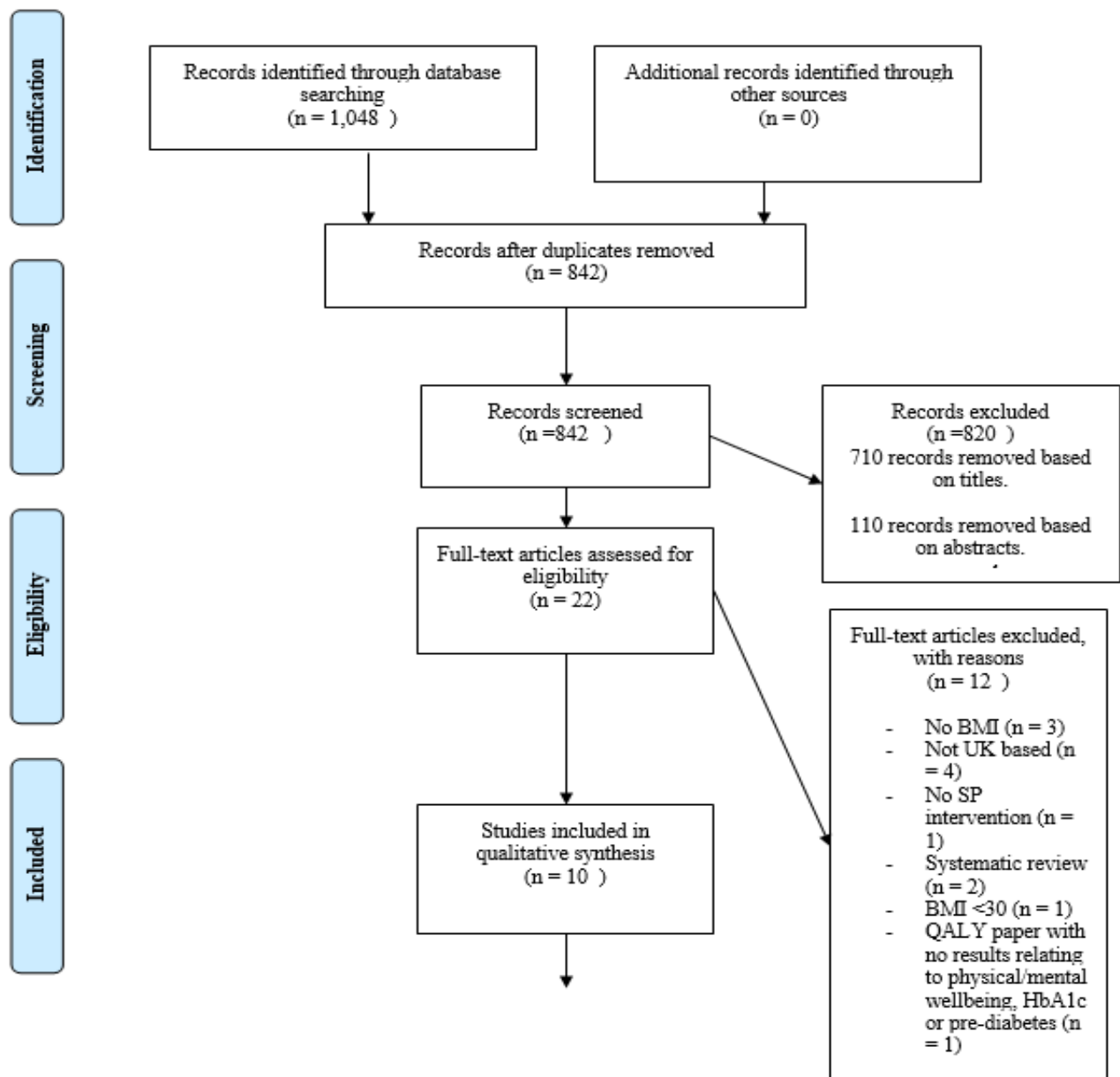
Only English language studies published in the UK were included, due to the fact that the MY LIFE programme would be conducted in the UK. The following databases were searched on the 5th of August 2021: The Cochrane Library (including the Cochrane Central Register of Controlled Trials (Central)); CINAHL Plus with Full Text; Applied Social Science Index and Abstracts (ASSIA); PsycINFO; PubMed Central; MEDLINE Ovid; Web of Science. Further search strategies included hand-searching references and citations, also known as ‘snowballing’ (Badampudi, Wohlin & Petersen, 2015). Grey literature searches were conducted through open-access sites, such as: CORE, BASE, Open Grey, Grey Source to increase the likelihood of discovering relevant literature. (See Appendix B).

The inclusion criteria included studies examining the impact of SP interventions in prediabetes management in primary care to improve physical and mental wellbeing in the UK between 2001 and 2021. No restrictions on study types were used for this review. The exclusion criteria consisted of studies that did not examine the use of SP interventions in prediabetes management in primary care to improve physical and mental wellbeing in the UK.

3.4.2 Study Selection

Titles and abstracts of papers were screened by one reviewer (AS) to determine their relevance in relation to the inclusion criteria. The screening of full texts was independently conducted by two reviewers (AS and ML). Upon reaching a consensus, articles that met the inclusion criteria were recorded. A PRISMA flow diagram was included to highlight the progression of the screening process. Upon completion of the screening process, ten studies were selected for quality assessment.

Figure 4. *Preferred Reporting Items for Systemic Reviews and Meta-Analyses (PRISMA) flow diagram for search outcomes and screening process.*



Data extraction forms were developed to assess the chosen studies and were compared against a set of data extraction criteria as follows: study characteristics, participant characteristics, intervention characteristics, data collection methods and outcomes. The included studies were critically appraised for methodological quality using the GRADE framework (Guyatt et al., 2011). The GRADE framework is a rating system that provides researchers an approach for developing and presenting evidence for SRs. Further, the GRADE framework provides guidelines for health care professionals to assist patients, recommending improved alternatives to clinical care (Guyatt et al., 2011; Mustafa et al, 2013).

The study design was assessed alongside the GRADE domains, which include:

- The clarity of the study's aims and objectives
- Risk of bias (by assessing each paper for risk of confounders, selection bias, allocation bias (if participants were allocated to either control or intervention at random), performance bias, detection bias, attrition bias and reporting bias)
- Indirectness (were the paper's population, intervention and outcomes expressed clearly, and were they relevant to the review question's population, interventions and outcomes)
- Imprecision (test for significant results)
- Publication bias (were the outcomes specified to be measured reported or was the paper absent of reported outcomes that showed no (or negative) effects?)

Following the above factors, the levels of quality were determined for each paper using the GRADE levels (Table 6).

Table 6. Quality Assessment of Included Studies

Study Author (Year) [Reference]	Study Design Certainty	Study Aim and Objective Clearly stated	Risk of Bias	Indirectness	Publication Bias	Test of Significance (Imprecision)	Overall Quality
Cliffe, Di Battista and Bishop (2021)	Low	Yes	Moderate Risk	No Serious Indirectness.	No Serious Risk.	No Information	Low
Buckley et al. (2019)	High	No	Low Risk	No Serious Indirectness.	No Serious Risk.	High Significance	High
Carroll, Borkoles and Polman(2007)	High	Yes	Low Risk	No Serious Indirectness.	No Serious Risk.	High Significance	High
Piper, Marossy, Griffiths And Adegboye (2017)	High	Yes	Low Risk	No Serious Indirectness.	No Serious Risk.	High Significance	High
Innes et al. (2019)	High	Yes	Moderate Risk (Omitted data from results).	No Serious Indirectness.	No Serious Risk.	High Significance	High
Lavin et al. (2006)	High	Yes	Low Risk.	No Serious Indirectness.	No Serious Risk.	High Significance – Wellbeing Low significance – Physiological	High
Nield and Kelly (2016)	Low	Yes	Low Risk.	No Serious Indirectness.	No Serious Risk.	High Significance	Low
Wallace, Myles, Holt and Van-Tam (2016)	High	Yes	Low Risk.	No Serious Indirectness.	No Serious Risk.	High Significance	High
Laws (2004)	High	Yes	Low Risk.	No Serious Indirectness.	High Risk (no test for significance).	No information	High
Long et al. (2014)	Low	Yes	Low Risk.	No Serious Indirectness.	No Serious Risk.	High Significance	Low

3.6 Study Characteristics

Table 7. Study characteristics and findings

Study Author Year [Reference]	Study design and methods	Objectives	Participants/Population	Outcomes (findings/results)
Cliffe, Di Battista and Bishop (2021)	Semi-structured interviews transcribed thematically (OBSERVATIONAL). via self-determination theory as a theoretical framework.	To access an adapted programme via videoconference to understand participant experience of weight-loss management.	People aged >18 with a BMI of 35 – 45. Referred by either primary care, secondary care or self-referral for weight management to an NHS dietetics service in Wales.	Ten themes were discovered during the video-conference intervention, relating to engagement and autonomy.
Buckley et al. (2019)	A mixed methods, pre-post design (QUASI-EXPERIMENTAL), followed by semi-structured interviews to gain perspective on the experiences during the intervention.	To explore the preliminary effects and acceptability of a co-produced physical activity referral intervention.	People with CVD, diabetes, mental health, musculoskeletal, and BMI >30.	Cardiorespiratory fitness (CRF) = significant change of +17%. Moderate to vigorous physical activity (MVPA) +46%. Systolic BP -7%. Waist to height ratio was unclear (-2%). Changes to psychosocial variables such as satisfaction or motivation towards physical activity were unchanged.
Carroll, Borkoles and Polman (2007)	Secondary analysis of randomised, controlled, 3 month, intensive, community-based, lifestyle intervention study. (To deduce the short-term effects of a non-dieting lifestyle intervention's impact on metabolic syndrome and psychological wellbeing among persons recruited to the WHEEL (Weight, Healthy Eating, and Exercise in Leeds) Study.	Healthy yet clinically obese (BMI >30) with no prior diagnoses related to CVD, kidney or liver disease, or T1 or T2DM, with a sedentary lifestyle (<2 days per week for <30 minutes of physical activity per week).	Intervention group showed significant improvements to VO2 compared to control group (P = 0.003). No significant difference found for BMI. Both groups experienced improvements for diastolic BP and High density lipoprotein (HDL). Psychological Wellbeing was significantly improved for the intervention group (P = 0.0005).
Piper, Marossy, Griffiths And Adegboye (2017)	Quasi-experimental study.	To determine if a diabetes prevention programme (DPP) delivered by a commercial weight management provider, using a UK primary care referral pathway could reduce the progression to type 2 diabetes (T2DM) in those diagnosed with non-diabetic hyperglycemia (NDH) being at high risk of developing T2DM).	Non-diabetic hyperglycaemic (NDH) participants with a fasting plasma glucose score of >5.5 to <6.9 mmol/L and a BMI of >30.	Mean reduction in HbA1c of 2.84 mmol/mol at 12 months (p <0.01). 38% of patients returned to normoglycemia and 3% developed T2DM at 12 months. BMI's reduced by 3.2kg/m2 at 12 months (p<0.01).

Table 7. Study characteristics and findings continued

Study Author Year [Reference]	Study design and methods	Objectives	Participants	Outcomes (findings/results)
Innes et al. (2019)	Parallel randomised control trial.	To evaluate the effectiveness of reducing body mass through the scalable NHS resource compared to a commercial resource-intensive weight-loss intervention; as well as a non-advice comparator group.	Participants with a BMI 30 to 45, with no current exercise plan in place and no current or recent dieting plan in place.	BMI reduced significantly for all 3 groups. With P value of .001 for both intervention groups compared to a p value of 0.05 for the control GYM group. Both interventions compared favourably as opposed to the control GYM group.
Lavin et al. (2006)	Quasi Experiment.	To assess participation and feasibility of referring obese patients from primary care to a commercial weight management group.	Participants with a BMI of >30 between 18 and 75 years of age, who were not pregnant with no recent affiliation to a weight management programme within the last 3 months.	Participants experienced an average weight loss of 5.4kg (6.4% baseline weight). Average weight loss over the total 24 weeks was 11.1 kg (11.3% baseline weight).
Nield and Kelly (2016)	Observation study.	To investigate the physical, psychological and dietary impact of a 12-week Specialist Community Weight Management Programme (SCWMP) on morbid and complex obesity patients.	Participants with a BMI ≥ 35 with a comorbidity or a BMI ≥ 40 without a comorbidity.	BMI – 3.82% to 6.26% weight reduction between the 3 and 6 month follow-up ($p < 0.001$). Improvements in physical activity levels, fruit and vegetable consumption, and self-esteem levels were also recorded ($p < 0.001$).
Wallace, Myles, Holt and Van-Tam (2016)	Pre-Post-test design.	To measure the effectiveness of a multi-component weight management service in achieving weight loss and psychological wellbeing among service users.	BMI >35 with related co-morbidities (Established cardiovascular disease, Osteoarthritis, Diabetes, Obstructive sleep apnoea, Severe hypertension, Dyslipidaemia, Polycystic ovarian syndrome, Metabolic syndrome) or a BMI >40 when no co-morbidities are present whilst registered with a General Practice in Derbyshire County.	Statistically significant improvements were found across weight reduction (4.9kg 12 weeks to 18.2kg 2 years) ($p = < 0.0001$). Reducing sample size for the psychological wellbeing questionnaire (CORE-OM) between 12 weeks and 2 years indicates significance is subject to skepticism, however still highly significant ($p = < 0.0001$ to $p < 0.0004$), suggesting a meaningful reduction in psychological distress.
Laws (2004)	Randomised control trial	To develop an evidence-based model to improve the management of obesity in primary care.	Obese adults aged 18-75, with a mean BMI of 36.9kg/M2	43% of those fully compliant patients experienced a weight-loss of 5% or more from baseline to 12 months follow-up.
Long et al. (2014)	Population-based prospective cohort study.	To examine whether improvements in health behaviours are associated with reduced risk of cardiovascular disease (CVD) in individuals with newly diagnosed type 2 diabetes.	Newly diagnosed diabetic patients aged between 40 and 69 years from the treatment phase of the ADDITION-Cambridge study.	CVD risk was inversely related to the number of positive health behaviours changed in the year after diabetes diagnosis. The relative risk for primary CVD event in individuals who did not change any health behaviour compared with those who adopted three/four healthy behaviours was (P for trend = .005).

3.7 Analysis and Synthesis

The analysis and synthesis of the selected 10 studies included in this SR took a thematic approach. The thematic analysis is a method used to synthesise included papers within an SR (Thomas & Harding, 2008). The thematic analysis in our SR involved aggregating and comparing findings from 10 chosen papers, of which four key themes were identified: cardiometabolic health, physical activity, psychological wellbeing, and weight loss. These key themes were selected on account of the level of homogeneity concerning the population, interventions, and outcomes agreed upon between the researchers (AS, ML) (Table 8).

Table 8: Key Themes

Theme 1: Cardiometabolic Health	Theme 2: Physical Activity	Theme 3: Psychological Wellbeing	Theme 4: Weight Loss
Buckley et al (2019)	Buckley et al (2019)	Buckley et al (2019)	Innes et al (2019)
Carroll et al (2007)	Nield and Kelly (2016)	Carroll et al (2007)	Lavin et al (2006)
Long et al (2014)	Long et al (2014)	Cliffe et al (2021)	Laws (2004)
Piper et al (2017)		Lavin et al (2006)	Nield and Kelly (2016)
		Nield and Kelly (2016)	Piper et al (2017)
		Wallace et al (2016)	Wallace et al (2016)

3.7.1 Summary of the studies

Buckley et al., (2019) examined the effects of a 12-week subsidised fitness centre access, including four behaviour change consultations for 32 adults with lifestyle-related health conditions (e.g., cardiovascular disease, diabetes, mental health problems, and musculoskeletal conditions). Participants attended four behaviour change consultations, with the aim of improving physical activity between baseline and follow-up. The primary outcome measures included changes in physical activity, cardiometabolic health indicators and psychological wellbeing assessment. Cardiometabolic health improved significantly ($p<.001$), including improvements to physical activity ($p=.013$), suggesting that the subsidised fitness programme was effective in reducing risk of cardiovascular disease and improving the health behaviours of participants, showing it was an effective intervention.

Carroll et al., (2007) studied the effects of a 12-week intensive, community-based, lifestyle intervention for premenopausal, clinically obese participants. The intervention examined the short-term effects of a non-dieting intervention. The intervention included supervised exercise and psycho-educational classes on healthy eating and body mass management methods within the theoretical, psychological framework of self-determination theory (SDT). Results of the intervention concerned outcomes relating to metabolic fitness (diastolic blood pressure and high density lipoprotein cholesterol) and psychological wellbeing (General Wellbeing 18-item questionnaire).

Cliffe et al., (2021) explored the effects of a behaviour change programme. The evaluation included semi-structured interviews, transcribed thematically. The study was conducted over 6-months and analysed participant perceptions of an online behaviour change intervention delivered by a registered dietician over Skype. 10 sessions were offered to 14 participants of which 10 participants completed. The outcomes from the thematic analysis included: reduced threat (of Covid-19) and reduced burden associated with engaging with an online intervention, compared with in-person, as this saved time, money, travelling time, and occupation disruption.

Innes et al., (2019) assessed the effects of a three-arm, parallel RCT evaluating the effectiveness of reducing body mass. The three arms included: a healthy weight programme, consisting of 10, 60-minute nutritional coaching sessions and 20 physical activity sessions. The second arm offered randomised participants an NHS resource which provided online information on proper nutrition and calorie tracking. The third arm was the control group, consisting of a gym induction and 12-weeks subsidised access to gym facilities. 25 participants were randomised onto the healthy weight programme (HWP), 25 onto the NHS intervention, and 26 were randomised to the control group. Outcome measures included body mass and BMI. Significant results ($p < 0.0001$) were recorded amongst both weight loss intervention groups (compared with the control group) at week 12.

Lavin et al., (2006) examined the effects of a quasi-experiment exploring a commercial weight loss programme aimed at obese participants referred through primary care. 170 participants were offered free slimming world sessions for 12 consecutive weeks. The main outcomes included changes in bodyweight (kg) and wellbeing at 12 and 24 weeks. Changes in weight loss were not significant. However, significant results ($p < 0.0001$) were recorded at week 12 and week 24 for wellbeing scores (e.g., feeling calm, more energy and less downhearted).

Laws (2004) explored the effects of the counterweight programme, which referred participants to group interventions designed to encourage participant goal setting for improved physical activity. The physical activity goals were provided by healthcare professionals from primary care. The goals included, adopting more physical output into everyday tasks, such as shopping, and adopting behavioural changes to physical activity. The study was conducted using a two-armed RCT and included 1256 participants from 80 GP practices. Participants from 18 practices were assigned to a control arm with no intervention, while the other surgeries were part of the intervention arm. The primary outcome measure was weight loss assessed at baseline and 12-month follow-up. Of the 51% of participants who completed the programme, 43% experienced a weight loss of 5% or more upon 12-month follow-up.

Long et al., (2014) examined the effects of a one-year population-based prospective cohort study to identify the exposure and outcome relationships associated to CVD and the number of health changes adopted. Participants included 867 newly diagnosed T2D participants. The primary outcome measure was cardiovascular disease event rate (CVD) in relation to health behaviour change outcomes (e.g., increasing physical activity, decreasing/stopping alcohol consumption, increasing both daily fiber and vitamin C intake, and decreasing both daily energy and total fat intake). The results indicated that reduced prevalence of CVD was greatest for participants who made at least 3-4 positive changes to their health behaviour change score.

Nield and Kelly (2016) investigated the physical, psychological, and dietary impact of a 6-month Specialist Community Weight Management Programme (SCWMP). The programme consisted of behaviour change consultations between participants and health-care professionals, via multiple mediums (e.g., telephone, face to face, groups and email). 288 patients with morbid and complex obesity were included. The primary outcome was weight change in accordance with the NICE guidelines, while the secondary outcomes included physical activity levels, fruit and vegetable intake, self-esteem, and BMI. 80% of patients experienced some weight loss by 3 months, while the resulting weight loss upon 6 months was statistically significant ($P<0.001$). Participants also reported significant improvements for all secondary outcomes at month 3 and month 6.

Piper et al (2017) explored the effects of a commercial weight management programme for 117 non-diabetic hyperglycaemic patients referred by primary care in the UK. This quasi-experimental study was conducted over 12 months, referring patients from 14 primary care practices to a Weight Watchers programme which included a 90 minute introductory session, followed by 48 weekly weight watchers community group meetings. The outcome measures included: mean change in HbA1c and fasting plasma glucose; mean weight loss (kg); mean BMI; and body weight change at 6 and 12 months. Significant reductions in HbA1c and BMI was experienced by participants at the 12-month follow-up ($P<0.001$).

Wallace et al (2016) explored the effects of referring 551 patients from GPs to a multi-component weight management service with the aim of achieving weight loss and improvements in psychological wellbeing. Participants were referred to lifestyle-modification programmes, including psychological support, behaviour change strategies, physical activity, dietetic advice, and occupational therapy. The results showed that 26% of participants experienced significant weight loss at 12-weeks and 50% of participants experienced significant weight loss at 24 weeks. Significant improvements for mental wellbeing scores were reported. However, due to attrition rates (352 participants recorded CORE-OM at baseline, while 18 participants recorded CORE-OM at 2 years), the significance level for mental wellbeing declined between 12-weeks and 2 years, from $p<0.0001$ to $p<0.001$ at one year, to $p<0.0004$ at 2 years follow-up.

3.7.2 Thematic Analysis

Theme 1 Cardiometabolic Health

Four of the studies assessed the effectiveness of SP interventions for improved cardiometabolic health (Buckley et al., 2019; Carroll et al., 2007; Long et al., 2014; Piper et al., 2017). Buckley et al. (2019) reported significant improvements in cardiometabolic health ($p<.001$), systolic blood pressure ($p<.001$) and significant improvements to diastolic blood pressure ($p<.004$) during a standard exercise referral scheme conducted over 12-weeks. Long et al. (2014) reported significant reductions in cardiovascular related disease effects when participants adopted three to four healthy behaviour changes ($p<0.005$).

Carroll et al. (2007) reported significant improvements ($p<0.001$) for metabolic health indicators including diastolic blood pressure and high-density lipoprotein cholesterol over a 12-week non-dieting lifestyle programme consisting of psycho-educational classes and supervised physical activity. Piper et al. (2017) reported significant results ($p<0.01$) for HbA1c upon 12-month follow-up during 48 weekly weight-watchers community group meetings. However, results for fasting plasma glucose levels did not produce significant results ($p= 0.267$).

Theme 2 Physical Activity

Three studies evaluated the effects of SP interventions on physical activity (Buckley et al., 2019; Nield & Kelly, 2016; Long et al., 2014). Buckley et al. (2019) applied a co-produced intervention (i.e., a procedure that includes the participant's feedback on the design of an intervention/programme), designed to improve physical activity through fitness centre activities, such as swimming, gym, and group exercise classes. Results for participants who engaged in physical activity were significant ($p < .013$). Nield and Kelly (2016) incorporated a seven-day physical activity recall questionnaire to assess physical activity (in minutes) during a 12-week intervention. The results for participants who engaged in physical activity were significant at 3 months and 6 months.

Long et al. (2014) investigated a physical activity intervention which used the Cancer-Norfolk physical activity Questionnaire. The questionnaire asked participants to provide information concerning diet and physical activity. Results were reported at baseline and one year. The results indicated that individuals who increased physical activity levels whilst abstaining/reducing alcohol consumption, reduced the risk of cardiovascular disease (CVD) events.

Theme 3 Psychological Wellbeing

Six studies measured the effects of SP on the psychological wellbeing of participants (Buckley et al., 2019; Carroll et al., 2007; Cliffe et al., 2021; Lavin et al., 2006; Nield & Kelly, 2016; Wallace et al., 2016). Buckley et al. (2019) conducted semi-structured interviews with 12 participants who participated in gym activities. Results suggested participant psychological needs satisfaction (i.e., indicators from questionnaire relating to, autonomy, competence, and relatedness) was unsuccessful. However, this was perhaps due to the lack of participant engagement. Participants responded positively to the exercise referral practitioners; however, some participants did not favour the gym. Others reported dissatisfaction with overcrowded gyms facilities. Cliffe et al. (2021) reported improvements to participant perceived threat and sense of burden, in comparison to perceptions of threat and burden when faced with in-person weight loss behaviour-change programmes. Carroll et al. (2007) reported significant outcomes for participant psychological wellbeing ($p < 0.0005$), using the General Wellbeing Schedule (an 18-item questionnaire used to determine participant distress/wellbeing scores) during a non-dieting weight loss intervention.

Lavin et al. (2006) reported significant improvements ($p<0.001$) in participant wellbeing at week-12, and week-24 during a Slimming World referral programme. The programme provided participants with advice on how to safely maintain a caloric-restricted diet in line with the National Obesity forum guidelines. Nield and Kelly (2016) reported significant improvements ($p<0.001$) to participant wellbeing, implementing the Rosenberg self-esteem scale. Participants experienced behaviour change consultations over 12-weeks. Wallace et al. (2016) used the CORE-OM questionnaire, a 34-item questionnaire which yielded significant results during a 2-year study conducted with 551 participants, upon recording at baseline

Theme 4 Weight Loss

Six of the included studies measured the effects of SP interventions on weight loss (Innes et al., 2019; Lavin et al., 2006; Laws, 2006; Nield & Kelly, 2016; Piper et al., 2017; Wallace et al., 2016). Innes et al. (2019) evaluated the effects of a parallel RCT, which offered participants either an online NHS resource for weight loss, a face-to-face gym focused intervention, or a control measure that offered a gym membership. The 12-week programme resulted in significant weight loss ($p<0.001$) for both intervention groups compared to the control group for BMI and weight (kg). Lavin et al. (2006) reported successful weight loss (5.4kg) during a 12-week commercial weight management programme. Participants who continued to engage in the programme after the 12-weeks experienced greater weight loss at 24-weeks (11.1kg).

Laws (2004) reported that participants experienced successful weight loss (kg) upon completion of the counterweight programme. The programme consisted of a minimum of 30-minute moderate to vigorous physical activity, provided to groups and individuals. Nield and Kelly (2016) reported significant weight loss (kg and BMI) ($p<0.001$). Piper et al. (2017) reported significant results in weight loss (kg and BMI) at six month and 12-month follow-up ($p<0.001$). Wallace et al. (2016) reported significant reductions in BMI and weight (kg) ($p<0.0001$) at week 12 to year 2.

3.8 Discussion

This systematic review identified ten studies, of which seven were of high quality and three were of low quality. The included studies identified positive associations of SP with its effects on cardiometabolic health (concerning heart disorders and metabolic disorders such as diabetes), physical activity, psychological wellbeing, and weight loss.

Three high quality studies (Buckley et al., 2019; Carroll et al., 2007; Piper et al., 2017) reported the effects of SP interventions for improved cardiometabolic health in relation to diastolic blood pressure. Two high quality studies (Buckley et al., 2019; Piper et al., 2017) and one low quality study (Long et al., 2014) reported improvements in cardiometabolic health, for systolic blood pressure. One high quality study (Piper et al., 2017) and one low quality study (Long et al., 2014) identified improved cardiometabolic health, pertaining to HbA1c. Two high quality studies (Piper et al., 2017; Carroll et al., 2007) identified improved cardiometabolic health in relation to high density lipoprotein cholesterol (HDL).

The evidence for the included studies pertaining to cardiometabolic health are promising with all four studies recording positive improvements to BP (Buckley et al., 2019; Carroll et al., 2007; Piper et al., 2017; Long et al., 2014). The outcome measures used to identify changes in HbA1c were identified differently, however, Piper et al. (2017) identified participant HbA1c via baseline and follow-up measurements from a GP within primary care. Long et al. (2014) first identified users following preidentified random capillary glucose and glycated haemoglobin test results, conducted in a previous cluster randomised trial.

High density lipoprotein cholesterol was measured by two high quality studies (Piper et al., 2017; Carroll et al., 2007). Both studies applied the same outcome measure to evaluate the resulting cholesterol levels at baseline and follow-up (lipid panel blood tests) a standard procedure used in NHS healthcare, to measure abnormalities in the blood relating to cholesterol and lipid levels.

One high quality study (Buckley et al., 2019) and two low quality studies (Nield & Kelly., 2016; Long et al., 2014) reported the effects of SP interventions for improved physical activity. Buckley et al. (2019) measured physical activity using accelerometers (devices attached to the extremity, or hip of a participant, to record intensity levels). Nield and Kelly (2016) incorporated 7-day physical activity recall (semi-structured) questionnaires, applied to estimate the amount of time participants spent engaging in physical activity. Long et al.

(2014) used the European prospective investigation into cancer-Norfolk physical activity questionnaire. The study timeframes were varied. Buckley et al. (2019) conducted a study over three months; Nield and Kelly's (2016) study lasted six months, and Long et al. (2014) conducted their study over one year. This indicates the success rate of SP interventions for improved physical activity, across multiple timeframes.

Four high quality studies (Buckley et al., 2019; Carroll et al., 2007; Lavin et al., 2006; Wallace et al., 2016) and two low quality studies (Nield & Kelly., 2016; Cliffe et al., 2021) reported on the effects of SP for improved psychological wellbeing. Buckley et al. (2019) measured psychological wellbeing using semi-structured interviews, to identify participant opinions concerning physical activity interventions. Results suggested that although participants felt positive about the support received during exercise referrals, they experienced issues concerning a busy gym atmosphere, including problems associated with insufficient staffing. Carroll et al. (2007) measured psychological wellbeing, using a general wellbeing questionnaire, resulting in positive significant change in participant wellbeing at 12-week follow-up ($p<0.001$).

Lavin et al. (2006) measured participant wellbeing at week-12 and week-24, using a series of questionnaires concerning participant's feelings of calmness, energy levels and feelings of downheartedness. Significant improvements were reported amongst participants at week-12 and were maintained at week-24 ($p<0.001$).

Cliffe et al. (2021) reported on participant group videoconference weight management programme in replace of an in-person programme. The programme was observational, and the 13 participants who were interviewed provided positive feedback, identifying a reduced feeling of burden and threat when engaging in a weight management programme from home, due to reduced need for travel, and a reduction occupational impediment. Nield and Kelly (2016) used the Rosenberg self-esteem scale questionnaire and found that successful weight management programmes improve self-esteem ($p<0.001$).

Wallace et al. (2016) used the CORE-OM questionnaire during a pre-test, post-test study, conducted over two years to measure changes in weight at baseline, 12 weeks, 24 weeks, one year, and two years. Positive significance was established at week-12, 24, year one, 18-months, and two years. However, the original population fell from 551 participants at baseline to 18 participants at two-year follow-up, which resulted in a significance drop from ($p<0.0001$) to ($p<0.004$).

Five high quality studies (Innes et al., 2019; Lavin et al., 2006; Laws et al., 2004; Piper et al., 2017; Wallace et al., 2016) and one low quality study (Nield and Kelly, 2016) explored the effects of SP interventions for improved weight loss. Results pertaining to weight loss suggest that increased weight loss is dependent on consistent adherence to the intervention and longevity of the study. Results from Innes et al. (2019) and Lavin et al. (2006) showed similar weight loss results for participants. Participants in the Lavin study reported weight loss of 5.4kg at 12-weeks. Innes et al. (2019) reported two weight loss outcomes for their parallel RCT, with 4.22kg weight loss in their healthy weight programme group, and 5.49kg weight loss in the NHS online resource group. Results from these studies suggests that weight loss can be experienced in both online and in-person intervention programmes. Nield and Kelly (2016) reported greater weight loss results when compared to Lavin's study due to study time-length. While Lavin reported positive weight loss at 12-weeks, Nield and Kelly conducted their weight loss study over 6-months. Participants were reported to have lost 4.95kg at 12-week follow-up and 8.41kg at 24-week follow-up.

Results from Piper et al. (2017) and Laws et al. (2004) were collected from studies lasting 1-year. Both studies reported positive weight loss results. Participant weight loss at 12-months was 10kg for those from Piper's study, while participants from Laws' study reported weight loss of 3.7kg at 3-months and 4.7kg at 12-months. The study conducted over the longest time-period experienced the greatest reduction in weight. Wallace et al. (2016) reported weight loss of 4.9kg at 12 weeks (similar to the aforementioned studies conducted over 12-weeks). However, upon two-year follow-up, participants reported an average weight loss of 18.2kg. Results from these studies are indicative of an increase in weight loss, the longer participants remain in a study.

3.9 Strengths and Limitations

A key strength of this SR was the implementation of concise inclusion and exclusion criteria. A second researcher (ML) was also consulted during the SR process, to reduce the risk of bias. To further instil internal validity, a protocol of the study was published within the PROSPERO website. Although attempts to increase the validity were made, the SR was unable to avoid all risk-factors. To ensure the relevance of the impact of SP interventions in primary care, studies were confined to those sourced within the UK.

It is recognised that most of the studies included were experimental in nature (RCT's) (see Table 7), however, they were not without limitations. One included study was a RCT which did not present *p*-value results, meaning significance was not accounted for (Laws, 2004). Attrition rates were another issue in some studies.

Researchers identified significant levels of attrition, stating that future studies would require detailed feedback if such an occurrence was to happen again. Wallace et al., (2019) reported attrition rates of 56% at baseline to week 12, 72% at week 24, 85% at one year, 92% at 18 months, and 96% at 2 years. However, Wallace also identified that participants missing at the next follow-up period, was due to different periods of participant enrolment onto the study. Varied enrolment resulted in inaccurate depictions of attrition. Nield and Kelly (2016), however, reported attrition rates of 39% from baseline to completion with no varied participant enrolment time. Lavin et al. (2006) identified a change in attrition between participants engaging in the free, 12-week period of the study (32%) and those participants who chose to remain engaged during the self-funded stage of the study (17% attrition). This, according to Lavin, identified participant's increased sense of value when a programme is self-funded.

Evidence from the selected articles identified a need for future research to be conducted over a longer time-period, to confirm the effectiveness of reducing risk of external factors (activities based outside the study's control) influencing change (Innes et al., 2019; Nield & Kelly, 2016; Piper et al., 2017). Seven of the included studies were experimental in nature, while the remaining three were observational. Those studies that did not include a control group, expressed how the need to identify a particular population was more important than the need for randomisation. Due to the nature of the research, it was not deemed necessary to include a control group, when studies conducted on patients with pre-existing comorbidities was essential, suggesting that observational studies remain efficacious.

3.10 Conclusion

This chapter presented the rationale for conducting a systematic review along with the key steps undertaken during the systematic review process. An outline of the inclusion and exclusion criteria was provided along with the study selection and quality grading of the included literature. The current systematic review addresses the thesis aims pertaining to social prescribing, and its perceived effects on prediabetes management of obese peoples within the UK. The results provided within this current systematic review helped inform this thesis of effective outcomes pertaining to the implementation of social prescribing programmes, that could be used for the benefit of the MY LIFE programme.

Results indicate a need for studies to be conducted over longer periods of time to experience greater weight loss outcomes for obese participants. In addition, the variety of research methods provided promising results, establishing positive outcomes for both online and face-to-face programmes, reporting at times, greater outcomes for psychological wellbeing and weight loss for online programmes. However, participant attrition was consistently associated with a decrease in clinical significance, suggesting that future studies may be inclined to consider improved communication methods with participants, enquiring into reasons for dropout.

Chapter 4 – Social Return on Investment (SROI)

4.1 MY LIFE research programme

The diabetes technician sent letters and emails to 117 potential candidates with prediabetes from 11 GP surgeries within Conwy West. Of those invited, 54 candidates were enrolled and completed baseline questionnaires. Twenty-four (n=24) participants completed follow-up questionnaires after 8-weeks. An SROI analysis was chosen to analyse the results of the baseline and follow-up questionnaires of the MY LIFE programme.

Ethical and governance approval was granted by the NHS Integrated Research Application System (IRAS) on July 1st, 2021 (IRAS ID: 300887). Ethical and governance approval was granted by the Healthcare and Medical Sciences Academic Ethics Committee of Bangor University (2021-16934) on July 5th, 2021. Ethical approval for this study ensured that dignity, safety and rights of all participants were upheld during the research study period (UK Research and Innovation, 2022) (Appendix H).

4.2 Introduction to SROI

SROI is a type of social cost-benefit-analysis (Social CBA), a systematic method recommended by the HM Treasury Green Book to assess interventions and their effects on wellbeing (HM Treasury, 2018). SROI is a framework that uses a combination of both quantitative and qualitative methods to assess value comparing costs and benefits (Cabinet Office, 2012). SROI uses the outcomes most important to the stakeholders and then assigns a monetary value to those outcomes. Examples of outcomes for the ‘MY LIFE’ programme include mental wellbeing, physical activity, and good overall health.

The main stages of this SROI evaluation include: identifying stakeholders, developing a theory of change, calculating inputs, evidencing and valuing outcomes, and estimating the SROI ratio (Cabinet Office, 2012) (See Figure 5).

Figure 5: Stages of SROI analysis

- 1. Identifying Stakeholders**
- 2. Developing a Theory of Change**
- 3. Calculating Inputs**
- 4. Evidencing and valuing outcomes**
- 5. Establishing Impact**
- 6. Estimating the SROI Ratio**

Diabetes Technician in the Conwy West Care Cluster with a diagnosis of pre-diabetes were the primary stakeholder. In addition, the NHS was a key stakeholder, as participation in the MY LIFE social prescribing programme is designed to reduce the demand for NHS health services.

4.3.1 Inclusion criteria

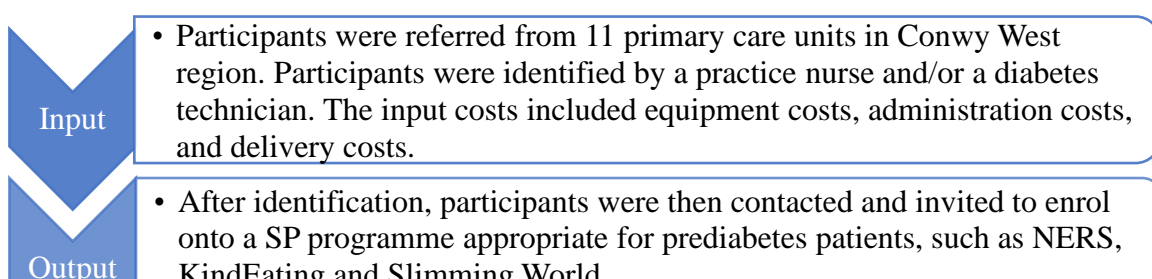
Those patients who met the requirements for this study included the following:

- Aged 18+
- BMI score of 30+ (i.e., those who are identified as being obese)
- Prediabetic (as identified by practice nurses and/or Diabetes Technician)

4.4 Developing a Theory of Change

A theory of change model was created to identify the outcomes expected to occur with participants of the MY LIFE programme. The theory of change was developed to illustrate the relationship between inputs, outputs, outcomes, and impact (Figure 6).

Figure 6. Theory of change overview



4.5 Calculating Inputs

The following cost categories were identified: equipment costs, administration costs, and delivery costs. Equipment costs for the Diabetes Technician included a laptop, mobile phone, and mobile phone contract. Administration costs for the Diabetes Technician included the salary for the Diabetes Technician (30 hours per week at £10.40 per hour). Delivery costs for each of the three SP programmes per participant (NERS, KindEating, and Slimming World) were supplied by the NHS (Table 9).

Equipment costs

The MY LIFE laptop was purchased for £947, and this cost was divided into the number of years the laptop's guarantee was supposed to last (five years), including an average annual cost. The MY LIFE mobile phone was purchased for £50 and was also divided into twelve months, to provide an average cost per annum.

Administration costs

Administration costs included the hourly rate of the Diabetes Technician, multiplied by the number of hours worked, multiplied by the number of days worked in a week, multiplied by the number of weeks in a year. This total was then divided by the number of participants (n=54), the Diabetes Technician worked with each year. The final calculations for equipment costs, administrative costs, and delivery costs were then added together to provide a total cost (Table 10).

Delivery costs

Delivery costs per participant associated to KindEating, Slimming World, NERS, and Diabetes Technician Only were provided by the lead dietician of the Conwy West region (M, Cliffe, Marion.Cliffe@wales.nhs.uk, April 28, 2022). Delivery costs per participant for NERS were provided by the fitness development manager of Conwy County Borough Council (Mark.orme@conwy.gov.uk, August 4, 2022). There were no extra delivery costs per participant for Diabetes Technician Only.

Table 9: Total costs per year for the ‘MY LIFE’ programme

Cost Category	Annual cost per Participant
Diabetes technician equipment costs	<ul style="list-style-type: none"> Including the cost of using a mobile and laptop, divided by their annual warranty over 5 years of use = £1.11 and £3.50 Total equipment costs = £4.61
Diabetes technician administration costs	<ul style="list-style-type: none"> £10.40 x 7.5 hours = £78 £78 x 4 days per week = £312 £312 x number of weeks in a year (52) = £16,224 £16,224 divided by the number of participants seen by technician per year (54) Total administration costs = £300
Programme delivery costs	
NERS	<ul style="list-style-type: none"> £258
Slimming World	<ul style="list-style-type: none"> £75
KindEating	<ul style="list-style-type: none"> £135.70

Table 10: Total Cost for Programme use per MY LIFE Participant

Participant ID	Programme	Programme/s Cost	Admin and Delivery costs	Total Cost per person
1005	NERS	£258	£304.61	£562.61
1014	KindEating	£135.70	£304.61	£440.31

401	Diabetes Technician Only	£0.00	£304.61	£304.61
802	Diabetes Technician Only	£0.00	£304.61	£304.61
803	Diabetes Technician Only	£0.00	£304.61	£304.61
813	NERS/Slimming World	£333	£304.61	£637.61
817	KindEating	£135.70	£304.61	£440.31
903	Slimming World	£75	£304.61	£379.61
906	Diabetes Technician Only	£0.00	£304.61	£304.61
907	Diabetes Technician Only	£0.00	£304.61	£304.61
909	KindEating	£135.70	£304.61	£440.31
911	Diabetes Technician Only	£0.00	£304.61	£304.61
101	Diabetes Technician Only	£0.00	£304.61	£304.61
107	KindEating	£135.70	£304.61	£440.31
109	NERS	£258	£304.61	£562.61
2001	KindEating	£135.70	£304.61	£440.31
2006	Diabetes Technician Only	£0.00	£304.61	£304.61
2011	KindEating	£135.70	£304.61	£440.31
701	Diabetes Technician Only	£0.00	£304.61	£304.61
713	Diabetes Technician Only	£0.00	£304.61	£304.61
715	KindEating	£135.70	£304.61	£440.31
318	Diabetes Technician Only	£0.00	£304.61	£304.61
8	KindEating	£135.70	£304.61	£440.31
15	Diabetes Technician Only	£0.00	£304.61	£304.61
Total cost per participant enrolled with a programme				£472
Total cost per participant enrolled with the Diabetes Technician Only				£304.61

4.6 Evidencing and Valuing Outcomes

4.6.1 Outcome measures

Fifty-four participants completed a baseline questionnaire, and twenty-four (44%) completed both a baseline and follow-up questionnaire. Data from questionnaires (see Appendix F & Appendix G) was used to gather information on participant health status, health service use, and outcomes pertaining to physical activity, mental wellbeing, and overall health. Data from the questionnaires was then collected to determine the number of participants who improved, worsened, or experienced no change for each outcome. Questionnaires included dichotomous and scaling approaches, to measure mental wellbeing, physical activity, and good overall health.

Data were included for 44% of participants who completed both baseline and 8-week questionnaires (n=24/54) (Table 11. Baseline scores and 8-week follow-up scores were compared to identify changes in participant scores using the SWEMWBS (mental wellbeing), EQ5D-5L (good overall health), and the SPAQ (physical activity).

Table 11: Demographic overview of complete cases for MY LIFE participants at 8-weeks

Category	MY LIFE Participants
Age at 8-weeks (n=24)	54% aged 49 and under
Gender percentage at 8-weeks (n=24)	67% Female 33% Male
Ethnic origin at 8-weeks (n=24)	100% White British
Average SWEMWBS Score at Baseline	25.5
Average SWEMWBS score at 8-weeks	27
Average EQ5D-5L at Baseline	0.761
Average EQ5D-5L at 8-weeks	0.834
Average SPAQ at Baseline	600 minutes
Average SPAQ at 8-weeks	662 minutes

Of the 24 complete cases of the MY LIFE programme, 12 participants enrolled with the Diabetes Technician plus a SP programme, while the other 12 remaining participants

continued to receive contact with the Diabetes Technician only. Both groups received continued contact with the Diabetes Technician on average every one to two weeks, receiving the same advice pertaining to nutrition, snacking, and physical activity. Both groups were also referred to online literature and video content, due to a lack of desire to attend face to face SP programme sessions during the pandemic.

Participant baseline (week one) and follow-up (week 8) contact with the Diabetes Technician lasted approximately 30-40 minutes. Catch-up calls at weeks 2, 4 and 6 were also incorporated into the 8-week study, with 10–15-minute calls, to determine whether or not participants were sufficiently coping with the parameters of the SP programmes, and or the advice of the technician.

Outcomes for participants enrolled in Diabetes Technician plus SP intervention

The results for participants who enrolled with the Diabetes Technician plus SP intervention showed improvements in good overall health and frequent moderate exercise:

- **Good Overall Health (EQ5D-5L):** 25% (n=3/12) of participants reported improvements of 10% or more in their EQ5D-5L results.
- **Frequent Moderate Exercise (Scottish Physical Activity Questionnaire):** 33% (n=4/12) of participants reported an increase of 10% or more in minutes of physical activity.

Outcomes for participants enrolled in Diabetes Technician Only

The results for participants who enrolled with the Diabetes Technician only also showed improvements in good overall health and frequent moderate exercise:

- **Good Overall Health (EQ5D-5L)** 17% (n=2/12) of participants reported improvements in their EQ5D-5L results of 10% or more.
- **Frequent Moderate Exercise (Scottish Physical Activity Questionnaire)** 33% (n=4/12) of participants reported an increase of 10% or more in minute of physical activity. 8% (n=1/12) of participants reported a reduction in minutes of physical activity of 10% or more.

4.6.2 Wellbeing valuation using the Social Value Calculator

Using the HACT Social Value Calculator, two outcome measures from the social value bank (SVB) were applied to outcomes at week 8 of the MY LIFE programme. These two outcome measures were ‘Good Overall Health’ and ‘Frequent Moderate Exercise’.

Once the data was quantified, wellbeing valuation was applied to assign monetary values (Table 12). The Social Value Calculator uses values from the HACT Social Value Bank (SVB), an online system that is constantly updated with methodologically robust social values.

Table 12: Examples of SVB monetary values for health outcomes

Health outcome	Average monetary value from SVB
Good overall health	£19,913 per person per year
Frequent Moderate Exercise	£4,272 per person per year

‘Good overall Health’ with a value of £19,913 per person per year was used to monetise changes in participant scores using the EQ5D-5L questionnaire. ‘Frequent Moderate Exercise’ with a value of £4,272 per person per year was used to monetise changes in participant scores using the SPAQ. These values were assigned to participants who improved by 10% or more at week-8 of the MY LIFE programme.

Good Overall Health

To quantify the total amount of value for ‘Good Overall Health’ received by each participant, those who experienced improvements of 10% or more at week 8 (n=5/24) were awarded a social value increase of £19,913 per year. Those whose scores decreased by 10% or more (n=0) were awarded a social value decrease of £19,913 per year. (Table 12).

Frequent Moderate Exercise

To quantify the total amount of value for ‘Frequent Moderate Exercise’ reported by each participant, those who experienced improvements of 10% or more at 8 weeks (n=7/24), were awarded a social value increase of £4,272 per year. Those who reported a reduction of 10% or more (n=1) were awarded a social value decrease of £4,272 per year. The net number of participants who reported improvements was multiplied by the value related to ‘Frequent Moderate Exercise’ (£4,272) (Table 12).

Deadweight, Attribution and Displacement

To avoid over-claiming on the outcomes of the MY LIFE programme, it is standard procedure in SROI analysis using the Social Value Calculator to consider deadweight, attribution, and displacement (Cabinet Office, 2012) (Table 14). The follow-up questionnaire indicated that the mean deadweight percentage was 43% for MY LIFE participants. This means that 43% of improvements would have happened anyway. The attribution percentage was 72%, meaning that 72% of the change was due to the MY LIFE programme. The displacement percentage was 0%, meaning that the MY LIFE programme did not displace any other activities meaningful to participants (Appendix G).

The total social value per participant experiencing good overall health enrolled in Diabetes Technician plus SP intervention, was £59,739. The total social value for each participant experiencing good overall health with Diabetes Technician Only, was £39,826 (Table 13).

The total social value awarded per participant for frequent moderate exercise enrolled in Diabetes Technician plus SP intervention, was £17,088. The total social value awarded to each participant for frequent moderate exercise with Diabetes Technician Only, was £12,816 (Table 13).

Table 13: Quantity of outcomes and total social value for programmes and Diabetes Technician Only

Outcomes: Week 8 (n=24)	Indicators	Net Quantity	Financial value	Total social value for programme and Diabetes Technician Only	Social value per participant per programme	Total social value per participant
Diabetes Technician plus SP Good Overall Health	EQ5D-5L: baseline to follow-up questionnaire	3/12 reported improved Good Overall Health	£19,913 per year for experiencing good overall health	£59,739	£4,978 (n=12)	£6,402
Diabetes Technician plus SP Frequent Moderate Exercise	SPAQ: baseline to follow-up questionnaire	4/12 reported improved Frequent Moderate Exercise	£4,272 per year for frequent moderate exercise	£17,088	£1,424 (n=12)	
Diabetes Technician Only Good Overall Health	EQ5D-5L: baseline to follow-up questionnaire	2/12 reported improved Good Overall Health	£19,913 per year for experiencing good overall health	£39,826	£3,319 (n=12)	£4,387
Diabetes Technician Only Frequent Moderate Exercise	SPAQ: baseline to follow-up questionnaire	3/12 reported improved Frequent Moderate Exercise	£4,272 per year for frequent moderate exercise	£12,816	£1,068 (n=12)	

Table 14: Quantity of outcomes and social value for Good overall health, and Frequent moderate exercise

Outcome for each programme:	Total social value per participant	Deadweight	Attribution	Displacement	Total social value per participant
Diabetes Technician plus SP intervention: Good overall health and Frequent moderate exercise	£6,402	43% (x 0.57)	28% (x 0.72)	0%	£2,627
Diabetes Technician Only: Good overall health and Frequent moderate exercise	£4,387	43% (x 0.57)	28% (x 0.72)	0%	£1,800

4.6.3 Wellbeing valuation using Mental Health Social Value Calculator

Applying the Mental Health Social Value Calculator, baseline and follow-up SWEMWBS scores were recorded, and monetary values were assigned to each participant (Trotter et al., 2017). A total social value for each of the MY LIFE participants has been calculated. Deadweight of 27% has been subtracted (Dancer, 2014), and the total social value for each programme is listed (Table 15).

Table 15: Social Value for each MY LIFE programme at week-8 using the Mental Health Social Value Calculator

Programme	ID	Baseline	Week 8	£ Value Baseline	£ Value week 8	Value change	Value - 27% Deadweight
NERS	1005	30	30	£25,470	£25,470	£0.00	£0.00
NERS	813	22	22	£19,947	£19,947	£0.00	£0.00
NERS	109	26	28	£24,144	£25,145	£1,001	£730.73
KE	1014	25	26	£23,295	£23,295	£0.00	£0.00
KE	817	29	28	£24,480	£23,563	-£917	-£669.41
KE	909	18	21	£10,523	£20,831	£10,308	£7,524.84
KE	107	16	19	£8,587	£16,701	£8,114	£5,923.22
KE	2001	28	27	£23,563	£23,563	£0.00	£0.00
KE	2011	24	26	£21,434	£23,295	£1,861	£1,358.53
KE	715	26	28	£24,144	£25,145	£1,001	£730.73
KE	8	18	24	£10,523	£23,383	£12,860	£9,387.80
SW	903	31	33	£25,811	£25,811	£0.00	£0.00
SW	813	22	22	£19,947	£19,947	£0.00	£0.00
NP	401	24	26	£21,434	£23,295	£1,861	£1,358.53
NP	802	25	27	£24,144	£25,145	£1,001	£730.73
NP	803	21	25	£20,831	£24,144	£3,313	£2,418.49
NP	906	28	31	£23,563	£25,132	£1,569	£1,145.37
NP	907	31	33	£25,132	£25,609	£477	£348.21
NP	911	28	30	£25,145	£25,470	£325	£237.25
NP	101	28	32	£23,563	£25,811	£2,248	£1,145.37
NP	2006	19	20	£16,653	£16,653	£0.00	£0.00
NP	701	26	29	£24,144	£25,470	£1,326	£967.98
NP	713	28	28	£23,563	£23,563	£0.00	£0.00
NP	318	29	33	£25,470	£25,811	£341	£248.93
NP	15	20	24	£16,701	£23,383	£6,682	£4,877.86
Total Social Value Per Participant enrolled with the Diabetes Technician Plus SP intervention				£2,082			
Total Social Value Per Participant enrolled only with the Diabetes Technician Only				£1,123			

4.6.4 Health Service Resource Use

Health service resource use was measured using the questionnaires completed by MY LIFE participants, to compare the number of visits made to NHS professionals. Participants were asked about the number of visits they made in the two months preceding the MY LIFE programme and in the first 8-weeks of their programme. The total annual cost saving for participants enrolled the Diabetes Technician plus SP intervention was £138 per participant at 8-weeks.

Table 16: Health service resource use for Diabetes Technician plus SP intervention

Service use between baseline and 8-weeks	2-months before programme	2-months during programme	Difference in visits	Cost per visit	Cost saving per 2-months	Cost saving per 12-months
GP visits	7	3	4	£39/visit ¹	£156	£936
Nurse	6	6	0	£44/visit ¹	£0	£0
Outpatient	2	1	1	£120/visit ¹	£120	£720
999 Ambulance	0	0	0	£231/visit ¹	£0	£0
A&E	0	0	0	£135/visit ¹	£0	£0
Total cost saving					£276	£1,656
Total cost saving per participant at 8-weeks (n=12)						£138

The total annual cost saving for participants enrolled with the Diabetes Technician Only was £167 per participant at 8-weeks.

Table 17: Health service resource use for Diabetes Technician Only participants

Service use between baseline and week 8	2-months before programme	2-months during programme	Difference in visits	Cost per visit	Cost saving per 2-months	Cost saving per 12-months
GP visits	8	2	6	£39/visit ¹	£234	£1,404
Nurse	9	4	5	£44/visit ¹	£220	£1,320
Outpatient	2	3	1	£120/visit ¹	-£120	-£720
999 Ambulance	0	0	0	£231/visit ¹	£0	£0
A&E	0	0	0	£135/visit ¹	£0	£0
Total cost saving					£334	£2,004
Total cost saving per week-8 participant (n=12)						£167

4.6.5 Calculating the SROI Ratios

SROI ratios were calculated for Diabetes Technician plus SP intervention and Diabetes Technician Only. The results indicated that for every £1 invested into Diabetes Technician plus SP intervention, the ratios ranged from £4.70 to £5.86 per MY LIFE participant (Table 18).

Table 18 : SROI ratio for Diabetes Technician plus SP intervention

	SROI Ratio (Social Value Calculator)	SROI Ratio (Mental Health Social Value Calculator)
Total social value per participant	£2,627	£2,082
NHS cost savings per participant	£138	£138
Total financial value per participant	£2,765	£2,220
Total cost per participant	£472	£472
SROI ratio	£5.86: £1	£4.70: £1

The results indicated that for every £1 invested into Diabetes Technician Only, the ratios ranged from £4.43 to £6.65 per MY LIFE participant (Table 19).

Table 19: SROI ratio for Diabetes Technician Only

	SROI Ratio (Social Value Calculator)	SROI Ratio (Mental Health Social Value Calculator)
Total social value per participant	£1800	£1,123
NHS cost savings per participant	£167	£167
Total financial value per participant	£1,967	£1,290
Total cost per participant	£304.61	£304.61
SROI ratio	£6.46: £1	£4.23: £1

4.7 Discussion

Results showed that participants enrolled with the Diabetes Technician plus SP intervention reported positive SROI ratios, ranging from £4.70 to £5.86 for every £1 invested. Participants enrolled with the Diabetes Technician Only reported results ranging from £4.23 to £6.46 for every £1 invested. These results showed similar SROI ratios for the Diabetes Technician plus SP intervention and the Diabetes Technician Only, suggesting that the Diabetes Technician was the key factor in generating social value. However, sample sizes were small and attendance at SP programmes were reduced as a result of COVID-19.

Results also suggest that participants of the Diabetes Technician plus SP intervention achieved greater social value, according to results from both the Social Value Calculator and the Mental Health Social Value Calculator (Tables 14 & 15). The social value scores for the Diabetes Technician Only were 54% to 69% of the total social value for the Diabetes Technician plus SP intervention. However, due to overall costs for delivering SP programmes, the SROI ratios were similar between the two groups. (Tables 18 & 19).

Strengths

Although previous UK studies have investigated the effects of SP interventions for weight-loss and reduced diabetic symptoms (Piper et al., 2017; Carroll et al., 2007), this is the first study to evaluate SP with an SROI evaluation framework for prediabetes patients.

Further, this study applied wellbeing evaluation using two different social value calculators. Wellbeing valuation is recommended by the HM Treasury Green Book (2018) to measure social CBA. The two calculators were the HACT Social Value Calculator and the HACT Mental Health Social Value Calculator.

Finally, the 'MY LIFE' programme provided patients with access to non-clinical-based SP interventions, which are recommended by the NHS' 'Healthier You' diabetes prevention programme, aimed at promoting weight-loss, improving diet, and increasing physical activity (NHS, 2015).

Limitations

First, this study was quasi-experimental in nature and lacked randomisation and a control group. Further, absence of a control group meant no comparisons were identified between an experimental group who received the SP intervention, and a control group, who received the usual standard of care (Akobeng, 2015). However, this issue was mitigated by the inclusion of participant follow-up questionnaires that accounted for deadweight, attribution, and displacement (Table 14).

Second, the application of social values from the SVB are dependent on the discretion of the researcher (Fujiwara et al., 2015). To elaborate, ‘frequent moderate exercise’ (£4,272 per person per year), could be replaced by ‘frequent mild exercise’ (£3,537 per person per year). The chosen outcome is dependent on whether the researcher determines the level of physical activity to be of moderate output or mild output. There is a level of subjectivity that could lead to upward bias, which refers to overestimation, which can lead to an inflated SROI ratio (Fujiwara et al., 2015).

Third, the results of this study are based on a small sample size (n=24). A small sample size may have resulted in increased variability. Increased variability could lead to a decreased likelihood that the results would reflect that of the general prediabetes population (Faber, & Fonseca, 2014).

Fourth, the participant retention rate for this study was 44%. Although this figure is less than half of the initial sample enrolled at baseline (n=54), this figure is within the average range of retention rates (i.e., 35% to 96%) for studies contributing to group-based weight management (Public Health England, 2018).

Fifth, participant adherence to programme use was not recorded. The Diabetes Technician was unable to determine how many SP programme sessions were attended by MY LIFE participants. Therefore, it was not possible to determine the number of participants who actually attended an SP programme and the dosage needed to produce an effect for each SP programme.

Finally, the ‘MY LIFE’ programme took place during the COVID-19 pandemic, which caused a delay in referrals to face-to-face SP programmes, and a reduction in programme uptake. Due to these circumstances, attendance at SP programmes decreased during COVID-

19, potentially resulting in less social value attributed to participants in the Diabetes Technician Only plus SP category (Long et al., 2022).

Recommendations for future research

Future research should continue to evaluate intervention-based SP support, alongside the professional support and guidance of the Diabetes Technician. Future research would also benefit from the inclusion of self-reporting frameworks for measuring physical activity (SPAQ), in conjunction with an objective measuring tool such as a pedometer, as research suggests that inclusion of both measures yields more efficacious readings (Ara et al., 2015). In addition, consideration of a larger sample size would also be important, as this would help to decrease study variability. Multiple sites would also be important for future research, as the MY LIFE programme only involved one site (Conwy West). Increasing the number of sites, would decrease variability and improve sample size. Monitoring participant attendance rates in SP programmes would further improve future research. Finally, future research should conduct studies of this nature once the effects of the COVID-19 pandemic have subsided. This may help to determine whether the social value reported from SP interventions will be higher during a non-COVID time-period.

4.8 Chapter Summary

This chapter reported on the six stages of SROI analysis. The stakeholders were identified, and a theory of change was developed. Inputs (total costs) were reported. The outcomes were measured using valid and reliable questionnaires, such as the EQ5D-5L, SPAQ, and SWEMWBS. The outcomes were valued using wellbeing valuation, from two different calculators (HACT Social Value Calculator, HACT Mental Health Social Value Calculator). Deadweight, attribution, and displacement were factored. NHS healthcare resource use was also reported. This chapter concluded by providing SROI ratios generated by the Diabetes Technician Only group and the Diabetes Technician plus SP intervention group.

Chapter 5: Conclusion

5.1 Introduction

Chapter 5 presents a summary of the main findings identified in the Systematic Review (SR) (Chapter 3), and the Social Return on Investment (SROI) (Chapter 4). These findings address the three research aims identified in this thesis: 1) To conduct an SR to identify if SP interventions in the UK are effective for the prevention of prediabetes management; 2) to develop a theory of change illustrating the expected impact of implementing SP for the prevention of prediabetes in the UK; 3) to determine the SROI of SP programmes for preventing prediabetes in the UK.

5.2 Main findings of the SR

Results from the SR suggest that participant enrolment onto an SP programme for prediabetes prevention resulted in improved cardiometabolic health, physical activity, psychological wellbeing, and weight-loss. These improved outcomes provided justification for delivering the MY LIFE programme. However, results from the ten included studies varied in time length, intervention methods (online, face-to-face), and included both high quality and low-quality studies. Overall, the results were positive, and identified a need for future research to be conducted over a longer time-period (Innes, et al., Nield & Kelly., 2016; Piper et al., 2017).

Further, the results indicated that online methods could generate improved mental wellbeing and weight loss for overweight or prediabetic patients (Innes et al., 2019; Cliffe et al., 2021). Future research should also implement methods to reduce participant attrition rates (Wallace et al., 2019; Nield & Kelly., 2016; Lavin et al., 2006). However, Lavin et al (2006) reported improved attrition rates when participants were required to self-fund subsequent weeks on a SP intervention.

Three high quality studies (Buckley et al., 2019; Carroll et al., 2007; Piper et al., 2017) and one low quality study (Long et al., 2014) reported improvements in cardiometabolic health in relation to systolic blood pressure (BP) diastolic BP, HbA1c, and high-density lipoprotein cholesterol levels. Of these studies, one study offered a 12-week subsidised fitness

programme for 32 adults (Buckley et al., 2019). One study offered a non-dieting intervention, with supervised exercise and psycho-educational classes on healthy eating (Carroll et al., 2007). One study incorporated a commercial weight management programme (Piper et al., 2017). The low-quality study used a physical activity intervention, in conjunction with the Cancer-Norfolk physical activity Questionnaire (Long et al., 2014).

One high quality study (Buckley et al., 2019) and two low quality studies (Nield & Kelly., 2016; Long et al., 2014) reported improvements to physical activity over varied periods of time, suggesting that the benefits of physical activity are attainable between 3 months and 12 months. One SP intervention included a 12-week subsidised fitness programme (Buckley et al., 2019). Another study used a 6-month Specialist Community Weight Management Programme (Nield & Kelly., 2016). The final study offered a physical activity intervention, including the Cancer Norfolk physical activity Questionnaire (Long et al., 2014).

Further, four high quality studies (Buckley et al., 2019; Carroll et al., 2007; Lavin et al., 2006; Wallace et al., 2016) and two low quality studies (Nield & Kelly., 2016; Cliffe et al., 2021) reported improved psychological wellbeing associated with SP interventions. Of these studies, one study conducted semi-structured interviews with indicators from a questionnaire relating to autonomy, competence, and relatedness. One study provided an 18-item questionnaire used to determine participant distress/wellbeing scores (Carroll et al., 2007). Another study provided three questionnaires measuring how calm/peaceful, energetic and/or downhearted participants felt (Lavin et al., 2006). Another study used the CORE-OM questionnaire, a five-point scale, 34 item questionnaire, used to report levels of wellbeing after therapy (Wallace et al., 2016). One low-quality study used the Rosenberg self-esteem scale (Nield & Kelly., 2016). The final study used video-recorded semi-structured interviews (Cliffe et al., 2021).

Finally, five high quality studies (Innes et al., 2019; Lavin et al., 2006; Laws et al., 2004; Piper et al., 2017; Wallace et al., 2016) reported the benefits of SP interventions for reductions in participant weight. One programme offered an online NHS resource for weight loss for one group, and a face-to-face gym focused intervention for the second, including a standard gym membership to the control group (Innes et al., 2019). Two studies offered a commercial weight management programme (Piper et al., 2017; Lavin et al., 2006). One study used a counterweight programme in which patients were referred to Weight Watchers (Laws et al., 2004). The final study offered an intensive lifestyle programme, incorporating

psychological support, behaviour change techniques, physical activity, and dietetic advice (Wallace et al., 2016)

Overall, the SR findings suggests that SP interventions focusing on weight loss and PA can improve physical and mental wellbeing in prediabetes patients. Evidence indicates that future research should explore whether using online methods could generate improved mental wellbeing and weight loss (Innes et al., 2019; Cliffe et al., 2021). In addition, future research should also implement methods to reduce participant attrition rates on SP programmes (Wallace et al., 2019; Nield & Kelly., 2016; Lavin et al., 2006). However, it is possible that attrition rates would be lower if participants were required to contribute financially to their SP interventions (Lavin et al, 2006).

5.3 Main findings of the SROI analysis

Results from the SROI analysis showed that SP programmes for prediabetes participants in the UK can generate positive results, with SROI ratios ranging from £4.70 to £5.86 for every £1 invested for Diabetes Technician plus SP intervention, and £4.23 to £6.46 for every £1 invested in participants enrolled with the Diabetes Technician Only. The data also shows that participants enrolled with either the Diabetes Technician plus SP intervention, or the Diabetes Technician Only resulted in reduced frequency of NHS health service resource use at the 8-week follow-up (Tables 16 & 17).

Further, results from this thesis suggests that positive social value outcomes were mainly a result of contact offered with the Diabetes Technician. It was estimated that between 54% and 69% of the social value awarded to participants of the ‘MY LIFE’ project, could be attributed to the Diabetes Technician. In addition, the Technician provided telephone support and motivation to participants every 2-weeks, including nutritional advice and guidance pertaining to increased PA.

Although results for participants of the Diabetes Technician plus SP intervention resulted in greater positive social value (i.e., £6,402 compared with £4,387), the increased cost associated with SP programmes resulted in the offset of social value generated. Further, results of these SP programmes, suggest that during the COVID-19 pandemic, the number of participants enrolled on SP programmes was reduced. This reduction could have resulted in an increased cost per person, plus a decrease social value per person, ultimately reducing the

overall SROI ratio for participants enrolled in the Diabetes Technician plus SP intervention programme.

5.4 Conclusion

The results from this research showed that the role of the Diabetes Technician was key in generating positive SROI ratios in the MY LIFE programme. Similarly, our SROI analysis showed that SP also elicited improved physical activity and mental wellbeing for prediabetes patients. Results also suggest that participant utilisation of NHS resources was reduced upon enrolment in the MY LIFE programme.

While the results of this study appear positive for SP interventions, there were limitations, such as, a lack of randomisation, a small sample size, the use of only one research site (Conwy West), insufficient monitoring of participant attendance, and reductions in availability of SP programmes due to COVID-19.

The results also showed that although the social value was greater for the Diabetes Technician plus SP intervention this greater social value did not ultimately compensate for the higher costs involved with delivering the SP programmes. However, due to the positive social value that was achieved within this study, future healthcare policy should support the role of the Diabetes Technician, while continuing to measure the effect of SP interventions in non-COVID time periods.

5.5 Recommendations for future research

1. Use multiple research sites with more than one Diabetes Technician

To improve robustness, future research should consider using multiple Diabetes Technicians within Wales and to a larger extent, the UK, including larger sample sizes in future research. This could reduce the chance of variability. Reduced standard deviation and reduced

variability would result in improved accuracy between the study sample and the prediabetes population of Conwy West (Lloyd-Evans et al., 2020; Barde & Barde, 2012).

2. Measure attendance

SP interventions undertaken during the MY LIFE programme would benefit from a more effective approach for monitoring participant programme adherence. Measurement of attendance is essential for determining how much dosage is needed to improve the outcomes of mental wellbeing, good overall health, physical activity.

3. Use Pedometers

Further research would benefit if participants were required to include the use of an objective measuring tool, such as a pedometer, when self-reporting minutes of physical activity (Public Health England, 2018). The inclusion of an objective measuring tool would ultimately improve the accuracy of the results, as current literature suggests that without an objective measuring tool, researchers must rely on participant memory and honesty. Future research would therefore benefit from the inclusion of objective measuring tools in conjunction with self-reporting questionnaires for physical activity (Ara et al., 2015; Brug et al., 2006).

4. Conduct study during a non-COVID period

Due to reduced participation of SP programmes during the COVID-19 pandemic, the cost per participant of delivering SP programmes was higher. The decline in uptake resulted in a greater cost per person, which in turn, reduced the social value reported during the SROI analysis. Further, future research should consider conducting a similar study when the effects of the COVID-19 pandemic have subsided, and when attendance is likely to be higher, and the availability of SP programmes is likely to increase.

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Appendices

Appendix A

Table A1. Patient/Problem or Population, Intervention, Comparator and Outcome(S) (PICO) framework for mixed methods search strategy.

Population	Intervention	(Comparison)	Outcomes
Pre-diabetic	Social Prescribing via Primary Care	(No comparison was included).	Improvements in physical and mental health wellbeing.

Appendix B

Table A2. Number of papers retrieved from respective databases

	ASSIA	Cinahl	Cochrane	Medline Ovid	PsycInfo	PubMed	Web of Science	Total
Initial number of records	25	14	35	40	30	23	39	1048
Number after removing duplicates	155	43	180	81	171	161	51	842

Appendix C

Table A3. List of full text-articles excluded and reasons for exclusion.

Full Paper Reference	Reason for exclusion
Li, J., Parrott, S., Sweeting, M., Farmer, A., Ross, J., Dack, C., ... & Murray, E. (2018). Cost-effectiveness of facilitated access to a self-management website, compared to usual care, for patients with type 2 diabetes (HeLP-Diabetes): randomized controlled trial. <i>Journal of medical Internet research</i> , 20(6). doi: 10.2196/jmir.9256	No mention of BMI. Utilise for discussion section.
Fazliana, M., Liyana, A. Z., Omar, A., Ambak, R., Nor, N. S. M., Shamsudin, U. K., ... & Aris, T. (2018). Effects of weight loss intervention on body composition and blood pressure among overweight and obese women: findings from the MyBFF@ home study. <i>BMC women's health</i> , 18(1), 25-32. doi: 10.1186/s12905-018-0592-2	Not UK based article.
Glasgow, R. E., Toobert, D. J., Barrera Jr, M., & Strycker, L. A. (2005). The Chronic Illness Resources Survey: cross-validation and sensitivity to intervention. <i>Health Education Research</i> , 20(4), 402-409. doi:10.1093/her/cyg14	Not UK based article.
Harrison, R. A., McNair, F., & Dugdill, L. (2005). Access to exercise referral schemes—a population based analysis. <i>Journal of Public Health</i> , 27(4), 326-330. doi:10.1093/pubmed/fdi048	No mention of either BMI or T2DM.
Mendes, R., Sousa, N., Reis, V. M., & Themudo-Barata, J. L. (2017). Implementing low-cost, community-based exercise programs for middle-aged and older patients with type 2 diabetes: what are the benefits for glycemic control and cardiovascular risk?. <i>International journal of environmental research and public health</i> , 14(9), 1057. doi:10.3390/ijerph14091057	Not UK based article.
Metcalfe, R. S., Babraj, J. A., Fawcner, S. G., & Vollaard, N. B. (2012). Towards the minimal amount of exercise for improving metabolic health: beneficial effects of reduced-exertion high-intensity interval training. <i>European journal of applied physiology</i> , 112(7), 2767-2775. doi.org/10.1007/s00421-011-2254-z	No mention of socially prescribed intervention.
Flint, S. W., Scaife, R., Kesterton, S., Humphreys, L., Copeland, R., Crank, H., ... & Carter, A. (2016). Sheffield Hallam staff wellness service: four-year follow-up of the impact on health indicators. <i>Perspectives in public health</i> , 136(5), 295-301. DOI: 10.1177/17579139166300	No mention of diabetes.
Frew, E. J., Bhatti, M., Win, K., Sitch, A., Lyon, A., Pallan, M., & Adab, P. (2014). Cost-effectiveness of a community-based physical activity programme for adults (Be Active) in the UK: an economic analysis within a natural experiment. <i>British Journal of Sports Medicine</i> , 48(3), 207-212. doi:10.1136/bjsports-2012-09120	Excluded due to the application of a Systematic Review.
Avery, L., Flynn, D., Dombrowski, S. U., Van Wersch, A., Sniehotta, F. F., & Trenell, M. I. (2015). Successful behavioural strategies to increase physical activity and improve glucose control in adults with Type 2 diabetes. <i>Diabetic Medicine</i> , 32(8), 1058-1062. DOI: 10.1111/dme.12738	Excluded due to the application of a Systematic Review and non UK based.
Cradock, K. A., ÓLaighin, G., Finucane, F. M., Gainforth, H. L., Quinlan, L. R., & Ginis, K. A. M. (2017). Behaviour change	Excluded due to the application of a Systematic Review and non UK based.

techniques targeting both diet and physical activity in type 2 diabetes: A systematic review and meta-analysis. *International Journal of Behavioral Nutrition and Physical Activity*, 14(1), 1-17. DOI 10.1186/s12966-016-0436-

Hardeman, W., Kinmonth, A. L., Michie, S., & Sutton, S. (2009). Impact of a physical activity intervention program on cognitive predictors of behaviour among adults at risk of Type 2 diabetes (ProActive randomised controlled trial). *International Journal of Behavioral Nutrition and Physical Activity*, 6(1), 1-10. doi:10.1186/1479-5868-6-16

Excluded due to a BMI of <30.

Steed, L., Barnard, M., Hurel, S., Jenkins, C., & Newman, S. (2014). How does change occur following a theoretically based self-management intervention for type 2 diabetes. *Psychology, health & medicine*, 19(5), 536-546. doi: 10.1080/13548506.2013.845301

Excluded due to an absence of BMI.

Appendix D Participant cover letter



Dear MY LIFE participant

We are writing to invite you to complete a baseline and follow-up questionnaire exploring your experience of the MY LIFE social prescribing programme.

The questionnaires are part of an evaluation of the MY LIFE programme. The evaluation is being organised by the NHS Conwy West Primary Care Cluster in collaboration with Bangor University.

The purpose of the questionnaires is to understand your perspective of the MY LIFE programme and any health changes you may have experienced. Any information you share will be treated as strictly confidential – you will not be identified in any report arising from this evaluation.

If you decide that you would like to complete the questionnaires, please read the attached participant information sheet, complete the consent form and return it to Adam Skinner at Bangor University, abp70b@bangor.ac.uk.

If you have any questions or would like to know more about this evaluation, please contact me at clare.hughes8@wales.nhs.uk

We look forward to hearing from you.

Kind regards

Clare Hughes

Clare Hughes
MY LIFE Project Manager
Conwy West Cluster
Betsi Cadwaladr University Health Board

Appendix E Participant information sheet for questionnaires



Participant Information Sheet for participants of MY LIFE social prescribing

You are invited to complete a pre- and post-questionnaire (approximately 15 minutes each) exploring your experience of the MY LIFE social prescribing project.

What is the purpose for the questionnaires?

The purpose of the questionnaires is to gain a better understanding of what's working about the MY LIFE project from the perspective of those who have experienced the programme.

Why have you been chosen?

You have been chosen because you have been referred by a NHS health professional to the MY LIFE project. The MY LIFE project team have kindly passed this information on to you.

What will happen if you decide to take part?

You will be invited to complete two questionnaires (approximately 15 minutes each), one before beginning and one immediately after your social prescribing programme.

What will happen if you decide to take part, but then want to withdraw?

You are free to withdraw from participating in this research at any time without giving a reason.

Will your answers on the questionnaire be kept confidential?

Yes. Your contact details and answers on the questionnaires will be stored on a confidential database. The information you share will be treated in confidence. You will not be identified in any reports or publications. Confidentiality will only be breached if participants disclose information that suggest that they or others are at risk of harm.

How will the data be stored?

The data will be stored on encrypted, password-protected laptops in accordance with Bangor University's standard operating procedures. All procedures for data collection, processing, storage and management will comply with the 2018 Data Protection Act. Access to data will be restricted to the research team. After completing the final report, data will be kept for five years which is the minimum institutional retention period for research data in compliance with the Bangor University Research Data Management Policy.

What will happen to this information at the end of study?

You will be sent a link to an end of study report where the findings will be written up.

Who is organising and funding the research?

This research is being funded by KESS 2, in partnership with Bangor University and Conwy West Primary Care Cluster.

What happens if you have any concerns about this project?

If you are concerned about any aspect of this research and would like to speak to someone, please contact Clare Hughes, MY LIFE Project Manager, Clare.Hughes8@wales.nhs.uk or Dr Mary Lynch, Bangor University, m.lynch@bangor.ac.uk

Contact for further information:

If you would like more information about the questionnaires, please contact research associate Adam Skinner, abp70b@bangor.ac.uk, at Bangor University.

Next steps:

If you decide that you would like to complete the questionnaires, please complete the enclosed consent form and email to abp70b@bangor.ac.uk

Thank you for helping us measure the impact of the MY LIFE project!

Appendix F Participant Baseline Questionnaire



"My Life" Project PILOT Participant Questionnaire

1.	Introduction																										
	Questionnaire to be completed by the Diabetes Technician during telephone consultations with pilot participants. All data recorded as part of this questionnaire is collected on a self-report basis.																										
2.	Diabetes UK Know Your Risk Questionnaire																										
2.1	The Know Your Risk tool is designed for people without a current diagnosis of diabetes and is intended to highlight a person's risk of developing Type 2 diabetes in the next 10 years.																										
2.2	<table border="1"> <thead> <tr> <th>Risk Factor</th> <th>Risk Scoring</th> <th>Score</th> </tr> </thead> <tbody> <tr> <td>What is your age? (The older you are, the higher your risk of developing Type 2 diabetes)</td> <td> <ul style="list-style-type: none"> 49 or younger (0) 50-59 (5) 60-69 (9) 70 or above (13) </td> <td></td> </tr> <tr> <td>What is your gender?</td> <td> <ul style="list-style-type: none"> Male (1) Female (0) </td> <td></td> </tr> <tr> <td>What is your ethnic background? (Some ethnic groups are more likely to develop Type 2 diabetes than others)</td> <td> <ul style="list-style-type: none"> South Asian (6) Black (6) Chinese (6) Mixed Ethnicity (6) White (0) None of these (6) </td> <td></td> </tr> <tr> <td>Do you have a parent, brother, sister and/or own child who has diabetes? (having a close relative with diabetes increases your risk of developing type 2 diabetes)</td> <td> <ul style="list-style-type: none"> Yes (5) No (0) </td> <td></td> </tr> <tr> <td>What is your waist circumference? (carrying excess body fat around your middle increases your risk of developing type 2 diabetes)</td> <td> <ul style="list-style-type: none"> 90cm (35.5in) or below (0) 90-99cm (25.5-39.2in) (4) 100-109cm (39.4-43.3in) (6) 110 cm (43.4in) or above (9) </td> <td></td> </tr> <tr> <td>What is your Body Mass Index?</td> <td> <ul style="list-style-type: none"> 25.0 or below (0) 25-29.9 (3) 30-34.9 (5) 35 or above (8) </td> <td></td> </tr> <tr> <td>Has a doctor ever told you that you have high blood pressure or given you medication for high blood pressure? (If you have been treated for high blood pressure it will contribute to your overall risk)</td> <td> <ul style="list-style-type: none"> Yes (5) No (0) </td> <td></td> </tr> </tbody> </table>			Risk Factor	Risk Scoring	Score	What is your age? (The older you are, the higher your risk of developing Type 2 diabetes)	<ul style="list-style-type: none"> 49 or younger (0) 50-59 (5) 60-69 (9) 70 or above (13) 		What is your gender?	<ul style="list-style-type: none"> Male (1) Female (0) 		What is your ethnic background? (Some ethnic groups are more likely to develop Type 2 diabetes than others)	<ul style="list-style-type: none"> South Asian (6) Black (6) Chinese (6) Mixed Ethnicity (6) White (0) None of these (6) 		Do you have a parent, brother, sister and/or own child who has diabetes? (having a close relative with diabetes increases your risk of developing type 2 diabetes)	<ul style="list-style-type: none"> Yes (5) No (0) 		What is your waist circumference? (carrying excess body fat around your middle increases your risk of developing type 2 diabetes)	<ul style="list-style-type: none"> 90cm (35.5in) or below (0) 90-99cm (25.5-39.2in) (4) 100-109cm (39.4-43.3in) (6) 110 cm (43.4in) or above (9) 		What is your Body Mass Index?	<ul style="list-style-type: none"> 25.0 or below (0) 25-29.9 (3) 30-34.9 (5) 35 or above (8) 		Has a doctor ever told you that you have high blood pressure or given you medication for high blood pressure? (If you have been treated for high blood pressure it will contribute to your overall risk)	<ul style="list-style-type: none"> Yes (5) No (0) 	
Risk Factor	Risk Scoring	Score																									
What is your age? (The older you are, the higher your risk of developing Type 2 diabetes)	<ul style="list-style-type: none"> 49 or younger (0) 50-59 (5) 60-69 (9) 70 or above (13) 																										
What is your gender?	<ul style="list-style-type: none"> Male (1) Female (0) 																										
What is your ethnic background? (Some ethnic groups are more likely to develop Type 2 diabetes than others)	<ul style="list-style-type: none"> South Asian (6) Black (6) Chinese (6) Mixed Ethnicity (6) White (0) None of these (6) 																										
Do you have a parent, brother, sister and/or own child who has diabetes? (having a close relative with diabetes increases your risk of developing type 2 diabetes)	<ul style="list-style-type: none"> Yes (5) No (0) 																										
What is your waist circumference? (carrying excess body fat around your middle increases your risk of developing type 2 diabetes)	<ul style="list-style-type: none"> 90cm (35.5in) or below (0) 90-99cm (25.5-39.2in) (4) 100-109cm (39.4-43.3in) (6) 110 cm (43.4in) or above (9) 																										
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Has a doctor ever told you that you have high blood pressure or given you medication for high blood pressure? (If you have been treated for high blood pressure it will contribute to your overall risk)	<ul style="list-style-type: none"> Yes (5) No (0) 																										

	Overall Risk Score=												
2.3	Know Your Risk Categories <table border="1"> <tr> <td>Score 0-6</td><td>Score 7-15</td><td>Score 16-24</td><td>Score 25-47</td></tr> <tr> <td>Low Risk</td><td>Increased Risk</td><td>Moderate Risk</td><td>Higher Risk</td></tr> </table> <p>*If score is Low Risk (0-6) or Increased Risk (7-15), participants follow pathway 1 for lifestyle changes. **If score is Moderate Risk (16-24) or Higher Risk (25-47), participants to be offered HbA1c test to identify a potential Pre Diabetes diagnosis.</p>	Score 0-6	Score 7-15	Score 16-24	Score 25-47	Low Risk	Increased Risk	Moderate Risk	Higher Risk				
Score 0-6	Score 7-15	Score 16-24	Score 25-47										
Low Risk	Increased Risk	Moderate Risk	Higher Risk										
3	General Health Measures												
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4.7	<p>Before question - What aspects of your eating habits do you feel that you need support with?</p> <p>After question - What if any of your eating habits have changed?</p>																																																															
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5.2	<p>Details of current activity levels (How many days in a typical week do you do physical activity, 30 mins or more?) Please tick how many days they are active</p> <p>None <input type="checkbox"/> 1-2 <input type="checkbox"/> 3-4 <input type="checkbox"/> 5-6 <input type="checkbox"/> 7 <input type="checkbox"/></p>																																																															
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6.2 Please tick the box that best describes your experience of OVER THE PAST 2 WEEKS

STATEMENTS	None of the time	Rarely	Some of the time	Often	All of the time
1. I've been feeling optimistic about the future					
2. I've been feeling useful					
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4. I've been dealing with problems well					
5. I've been thinking clearly					
6. I've been feeling close to other people					
7. I've been able to make up my own mind about things					

7.	Health-related quality of life	
7.1	Under each heading, please tick the ONE box that best describes YOUR HEALTH TODAY	
	Mobility	Tick one box below
	I have no problems in walking about	
	I have slight problems in walking about	
	I have moderate problems in walking about	
	I have severe problems in walking about	
	I am unable to walk about	
	Self-Care	Tick one box below
	I have no problems washing or dressing myself	
	I have slight problems washing or dressing myself	
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	Usual Activities (e.g., work, study, housework, leisure activity)	Tick one box below
	I have no problems doing my usual activities	
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	Anxiety / Depression	Tick one box below
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8.	Living Ambitions
	<p>ON a scale of 1 – 10, how would you score the following:</p> <ol style="list-style-type: none"> 1) Your general wellbeing? 2) Your mental wellbeing? 3) Your physical health? 4) Your diet/ healthy eating? 5) Your motivation to improve your health and wellbeing? 6) Your knowledge and skills to be able to make lifestyle changes to reduce the risk of developing diabetes in the future? 7) Your overall happiness?
9.	Post project
9.1	What knowledge and skills have you learned from the 'MY LIFE' project?
9.2	<p>I am confident that I will continue this programme without 'MY LIFE'...</p> <ul style="list-style-type: none"> • Strongly Agree • Agree • Undecided • Disagree • Strongly Disagree
9.3	<p>I am likely to sustain the lifestyle changes that I have made through MY LIFE...</p> <ul style="list-style-type: none"> • Strongly Agree • Agree • Undecided • Disagree • Strongly Disagree

Appendix G Participant follow-up questionnaires



"My Life" Project PILOT Participant Questionnaire 16 Week Follow Up

1.	Introduction																
	Questionnaire to be completed by the Diabetes Technician during telephone consultations with pilot participants.																
2	General Health Measures																
2.1	<table border="1"> <tr> <td>Weight (kg) (stone/ lbs)</td> <td>Height (cm)(ft/ inch)</td> <td>BMI</td> <td>HbA1c (if relevant)</td> <td>Waist Circumference</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>					Weight (kg) (stone/ lbs)	Height (cm)(ft/ inch)	BMI	HbA1c (if relevant)	Waist Circumference							
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3.1	<p>How many portions of fruit and vegetables did you eat the <u>previous day</u>?</p> <ul style="list-style-type: none"> • Five or more • Four • Three • Two • One • None
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4.6	<p>What type of opportunities would you be interested in participating in (this can be exercise/ work/ play/ individual activities/ group activities etc.)?</p>
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5.1	<p>In terms of your overall wellbeing, are there any issues, concerns or attributing factors that you would like to be supported with? (e.g. loneliness/ anxiety/ finance)</p>

5.2 Please tick the box that best describes your experience of OVER THE PAST 2 WEEKS

STATEMENTS	None of the time	Rarely	Some of the time	Often	All of the time
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7.	Living ambitions
	<p>ON a scale of 1 – 10, how would you score the following:</p> <p>8) Your general wellbeing?</p> <p>9) Your mental wellbeing?</p> <p>10) Your physical health?</p> <p>11) Your diet/ healthy eating?</p> <p>12) Your motivation to improve your health and wellbeing?</p> <p>13) Your knowledge and skills to make lifestyle changes to reduce the risk of developing diabetes?</p> <p>14) Your overall happiness?</p>
8.	16-week questions
8.1	What knowledge and skills have you learned from the 'MY LIFE' project?
8.2	<p>I am confident that I will continue this programme without 'MY LIFE'...</p> <ul style="list-style-type: none"> • Strongly Agree • Agree • Undecided • Disagree • Strongly Disagree
8.3	<p>I am likely to sustain the lifestyle changes that I have made through MY LIFE...</p> <ul style="list-style-type: none"> • Strongly Agree • Agree • Undecided • Disagree • Strongly Disagree
8.4	<p>Please circle the number on the scale which best indicates how much your personal wellbeing has changed since starting the MY LIFE project: (i.e., 0 = stayed the same)</p> <p>-5 -4 -3 -2 -1 0 +1 +2 +3 +4 +5</p> <p>└───┴───┴───┴───┴───┴───┴───┴───┴───┴───┴───┘</p> <p>My own wellbeing has worsened I My own wellbeing has improved</p>
8.5	<p>How much of this change is due to the MY LIFE project?</p> <p>None Small amount Moderate amount Large amount Very large amount</p>

8.6	<p>How much of this change would have happened anyway (if you had not participated in the MY LIFE project)?</p> <p>None Small amount Moderate amount Large amount Very large amount</p>
8.7	<p>By participating in the MY LIFE project over the last several months, how much have you had to give up other activities that benefitted your health and wellbeing?</p> <p>None Small amount Moderate amount Large amount Very large amount</p>
8.8	<p>When the MY LIFE project finishes, how long do you think the benefits of the programme will last?</p> <p>Less than 1 month 3 months 6 months One year More than one year</p>
	<p>8.9 In your own words please describe how you have experienced this programme? (Dictaphone)</p>

Appendix H Ethical Consent Form



Ymchwil Iechyd
a Gofal Cymru
Health and Care
Research Wales



Dr Ned Hartfiel
Research Officer
Bangor University
Centre for Health Economics and Medicines Evaluation
Ardudwy Building, Normal Site
Bangor University
LL57 2PG

Email: approvals@hra.nhs.uk

01 July 2021

Dear Dr Hartfiel

**HRA and Health and Care
Research Wales (HCRW)
Approval Letter**

Study title:	Social return on investment of the MY LIFE programme: supporting people in Conwy West to live healthy and active lives
IRAS project ID:	300887
REC reference:	21/EE/0174
Sponsor	Bangor University

I am pleased to confirm that [HRA and Health and Care Research Wales \(HCRW\) Approval](#) has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see [IRAS Help](#) for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to [obtain local agreement](#) in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "[After Ethical Review – guidance for sponsors and investigators](#)", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

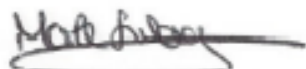
The [HRA website](#) also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **300887**. Please quote this on all correspondence.

Yours sincerely,



Mark Sidaway

Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Dr Mary Lynch*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of materials calling attention of potential participants to the research	version 8	29 March 2021
Covering letter on headed paper		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Bangor University Professional Indemnity Letter]	version 1	15 May 2021
Interview schedules or topic guides for participants [Interview Schedule]	version 1	12 May 2021
IRAS Application Form [IRAS_Form_10062021]		10 June 2021
Letter from funder		31 March 2021
Letter from sponsor		30 March 2021
Letters of invitation to participant [Cover letter for participants]	version 1	14 May 2021
Non-validated questionnaire [Baseline questionnaire]	version 1	15 May 2021
Non-validated questionnaire [Follow-up questionnaire]	version 1	15 May 2021
Organisation Information Document	version 1	09 June 2021
Participant consent form [Consent form for questionnaires]	version 1	12 May 2021
Participant consent form [Consent form for interviews]	version 1	12 May 2021
Participant information sheet (PIS) [PIS for participants completing questionnaires]	version 2	23 June 2021
Participant information sheet (PIS) [PIS for participants completing interviews]	version 2	23 June 2021
Research protocol or project proposal [SROI My Life Protocol]	version 1	14 May 2021
Schedule of Events or SoECAT		
Summary CV for Chief Investigator (CI) [Summary CV for Chief Investigator]	version 1	02 June 2021
Summary CV for student [Summary CV for student]	version 1	02 June 2021
Summary CV for supervisor (student research) [Summary CV for Supervisor]	version 1	02 June 2021
Summary of any applicable exclusions to sponsor insurance (non-NHS sponsors only) [Bangor University Medical Malpractice Letter]	version 1	15 May 2021
Summary, synopsis or diagram (flowchart) of protocol in non technical language	version 1	09 June 2021

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
There is only one participating NHS organisation therefore there is only one site type.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.	An Organisation Information Document has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.	No study funding will be provided to sites as per the Organisational Information Document	A Principal Investigator should be appointed at study sites	No Honorary Research Contracts, Letters of Access or pre-engagement checks are expected for local staff employed by the participating NHS organisations. Where arrangements are not already in place, research staff not employed by the NHS host organisation undertaking any of the research activities listed in the research application would be expected to obtain a Letter of Access based on standard DBS checks and occupational health clearance.

