SPRING

Social Prescribing in Mental Health Study

A Mental Health Social Prescribing trial (Mind Cymru)

A collaboration between

Protocol Version 3

04.11.2019

IRAS number	260516

SIGNATURE PAGE

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

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

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

For and on behalf of the Study Sponsor:

Signature: Date:
...../...../.....
.....

Name: Dr Louise Bright

Position: Director of Research and Business Engagement

Chief Investigator:

Signature: Date:
..../...../.....

Name: Professor Mark Llewellyn

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STUDY SUMMARY

STUDY TITLE	A MENTAL HEALTH SOCIAL PRESCRIBING TRIAL (MIND CYMRU)
Internal ref. no. (or short title)	SPRING
Study Design	Mixed-methods study involving a randomised waitlist evaluation using a co-productive participatory approach (see 5.0) and qualitative methods
Study Participants	People experiencing mild/moderate mental health and/or emotional wellbeing disorders (e.g. anxiety or depression) who are aged over 18 years and registered with a GP in Wales (see 7.0)
Planned Size of Sample	Expecting a minimum of 1,500 referrals with 5% attrition rate (see 7.2) for the waitlist trial. Expecting 35-40 participants for the participant interviews.
Follow-up duration (if applicable)	3 months following the end of the intervention
Planned Study Period	The full study will run from May 2019 to May 2021. Participants will be in the study for up to six months. Participants will either participate in an interview on a single occasion or be invited to participate in repeated interviews to capture different stages. This will be a maximum of three occasions over six months.
Research Question/Aim(s)	To evaluate the social prescribing service's impact on individual and system-level outcomes, compared to care as usual (see 3.0)

FUNDING AND SUPPORT IN KIND

FUNDER(S)	FINANCIAL AND NON FINANCIAL SUPPORT GIVEN
Welsh Government Contact: James Roberts – Mental Health & Vulnerable Groups Division, Health and Social Services. Welsh Government, Cardiff, CF10 3NQ Phone: 03000 253253 Email: James.Roberts017@gov.wales	£129,979.64

ROLE OF STUDY SPONSOR AND FUNDER

Welsh Government have provided the funding for this study. Mind Cymru is delivering the intervention and University of South Wales (USW) is the sponsor.

Role of USW: USW is working as an independent organisation to provide an evaluation to measure impact of the Mind Cymru social prescribing intervention, without further involvement of the funder. USW will work in partnership with Mind Cymru on designing the study, data collection and data analysis.

Role of Welsh Government: The Welsh Government have provided the funding for this study. The study was awarded through a competitive process and the application was reviewed internally before being awarded to USW. Welsh Government will receive regular reports about progress from the project team in Mind Cymru.

ROLE OF STUDY PARTNER – MIND CYMRU

Mind Cymru is responsible for managing the overall project. Particularly, their role will be to design and co-ordinate the service, partnering with four local Minds who will deliver the social prescribing intervention, organise recruitment and contact participants to receive consent.

Local Mind link workers will also be responsible for collecting data at the data collection points during service delivery, either over the phone or face-to-face during an appointment. Mind Cymru staff will be responsible for collecting follow-up data.

The USW research team have also worked with Mind Cymru to co-produce and develop the study design.

Mind Cymru is responsible for funder reporting. They will collate information from the study team and add this to their wider funder report.

The Mind Cymru website will host a page about SPRING, which holds all of the information available to participants, participant information sheets, consent forms, copies of the measurements scales and contact information for Mind Cymru. The website will also be used to disseminate findings once the study has been completed.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

The study team consulted the PRIME SUPER group in March 2019.

Colleagues at Mind Cymru have worked with the study team on the study design and logistics. They will be responsible for data collection, collection of consent from participants, anonymisation of data and transfer of anonymised study data to USW.

PROTOCOL CONTRIBUTORS

The sponsors, the research team at USW (Professor Mark Llewellyn, Professor Mark Williams, Dr Carolyn Wallace and Megan Elliott), are responsible for the study design (in partnership with the PRIME SUPER group), conducting the study, data analysis and interpretation, writing reports and dissemination of results.

The study has been designed in collaboration with colleagues at Mind Cymru, GPs within each of the Primary Care Cluster sites through Primary Care cluster meetings in Taff Ely, North Denbighshire and the Red Kite cluster, and local Mind link workers who will deliver the social prescribing intervention.

The study team have also presented the study design to the PRIME Centre Wales SUPER group for public and patient involvement (http://www.primecentre.wales/lay-involvement.php) – their comments have been incorporated within this document.

KEY WORDS

- Mental health
- Social prescribing
- Link worker
- Well-being

SPRING

A MENTAL HEALTH SOCIAL PRESCRIBING TRIAL (MIND CYMRU)

1.0 BACKGROUND

Social prescribing is an umbrella term to describe ways of linking people to sources of community-based, non-medical support. There is no fixed definition of social prescribing.

In Wales, social prescribing has many models which require the NHS and third sector organisations to work closely together. These involve referral to a link worker/community connector/social prescriber from primary care or another referral route, such as social work or housing. These roles all practice social prescribing, which includes a 'what matters' conversation, co-productive goal setting, motivational interviewing and coaching, followed by referral to third sector and community groups/professionals for support and activity to meet the person's individual goals.

Social prescribing is being widely implemented and has support from Welsh Government (WG, 2016). However, there is limited research evidence to judge its effectiveness, who benefits (if at all) and its value for money (Bickerdike *et al.,* 2017; Price *et al.,* 2017). Public Health Wales identified gaps in the published evidence for social prescribing, particularly in the evaluation of social prescribing projects in primary care in Wales (Primary Care Hub, 2018). It is therefore important to employ more rigorous and high-quality methods to evaluating social prescribing interventions in the community.

As part of a Welsh Government Third Sector grant for delivering a social prescribing pilot with a focus on mental health, Mind Cymru are undertaking a research study with four local Mind Cymru organisations across Wales to create and test a model of social prescribing. As part of this initiative, a link worker will work with the patient across up to 5 appointments to discuss their needs, goals and future steps. A link worker uses a holistic approach when co-creating a support plan that looks to resolve the root cause(s) of a problem that can make a person unwell.

This study will conduct an evaluation alongside the implementation and delivery of the Mind Cymru social prescribing intervention, using a randomised waitlist trial evaluation method. Participants will either receive the social prescribing intervention within 5 working days of giving consent and collecting baseline data, or 20 working days after consent and baseline data collection. This will allow the researchers to draw comparisons between the immediate intervention group and the waitlist controls, who continue to receive usual care. This will also provide a more robust evidence base for social prescribing interventions. The study will use measures of quality of life, well-being and loneliness, as well as service data to see if the intervention has an effect.

1.1.LAY SUMMARY

Social prescribing is a way of understanding the things that are important to a person and then using these to find groups and resources in their local community that can help them meet their goals and understand their problems. Social prescribing can be used with people who have physical health problems, mental health problems, social problems such as loneliness or financial/housing problems.

The Welsh Government has supported the creation of these social prescribing services across Wales. However, the evidence showing that social prescribing is a good way of improving a person's well-being and quality of life is not very strong. It is important for researchers to run more studies looking at social prescribing using more high-quality research methods.

This study aims to do this by running an evaluation of a new social prescribing service delivered by Mind Cymru in four communities in Wales. Mind Cymru have made a new social prescribing service, where a link worker works with a patient who has mild/moderate mental or emotional health problems, to understand their needs and set them goals for the future. The link worker will then help them find a service in their local community that might help them achieve their goals.

The study uses a waitlist trial, which means that some participants will get to meet the link worker and have the intervention straight away, while others will have to wait for 20 working days. From this, the researchers can compare the people who had the intervention straight away with the people who had to wait. Scores on well-being, quality of life and loneliness questionnaires will be used to see the effects of the intervention on patients, whilst information like patient attendance at the GP surgery will be used to see if there is a difference in the patient's use of health services.

2.0 RATIONALE

There is limited existing research evidence to judge the effectiveness, benefits and value for money of social prescribing (Bickerdike *et al*., 2017; Price *et al*., 2017). To evaluate the Mind Cymru social prescribing service for mental health, this study will employ a waitlist trial design.

Within the waitlist trial participants will be randomised to receive the service immediately, or will have to wait for 20 working days before they receive the intervention. This design was chosen as it provides a control group of participants to compare the intervention group with, but means that all participants still receive the intervention at some point. Throughout the study, participants continue to receive usual care from their GP.

2.1 LINKS TO POLICY

Aligning the study to key policies was an important requirement in the design of this evaluation.

Taking Wales Forward: The programme for government – sets out how the Welsh Government plans to deliver more and better jobs through a stronger, fairer economy, improve and reform public services, and build a united, connected and sustainable Wales. It has four key themes, of which the second, 'Healthy and Active' is key to the Mental Health Social Prescribing project.

A number of well-being objectives from 'Taking Wales Forward', along with 'Prosperity for all: the national strategy' and 'the Wellbeing statement 2017' have been mapped against the work of this study (Table 1).

Table 1.

Objectives within 'Healthy and Active' Key Theme	**Descriptor**
DELIVER QUALITY HEALTH AND CARE SERVICES FIT FOR THE FUTURE	*Deliver a tangible shift in the provision of health and care services into communities, and away from hospitals, and shift the emphasis from treating illness to well-being.*
DELIVER QUALITY HEALTH AND CARE SERVICES FIT FOR THE FUTURE	*Deliver a tangible shift in the provision of health and care services into communities, and away from hospitals, and shift the emphasis from treating illness to well-being.*
PROMOTE GOOD HEALTH AND WELL-BEING FOR EVERYONE	*Support and encourage a substantial increase in people's physical activity, adopting a collaborative approach from all agencies involved in the promotion of healthier lifestyles, and drawing on Wales' significant natural resources.*

	Develop innovative, community approaches to encouraging more active lifestyles and improving nutrition through the Well-being Bond.

There is also an overlap between the well-being duties and the well-being goals within the 'Well-being of Future Generations (Wales) Act (2015) and the kinds of outcomes that the study aims to achieve. There are seven well-being goals for Wales, of which four (in bold below) are directly relevant to the study. Their connection to the Together for Mental Health High Level Outcomes are highlighted in Table 2.

Table 2.

Well-being goals	High level outcomes
A HEALTHIER WALES	*Population-wide physical and mental well-being is improved; people live longer, in better health and as independently as possible, for as long as possible.* *People in Wales have the information and support they need to sustain and improve their mental health and self-manage mental health problems.* *People of all ages experience sustained improvement to their mental health and wellbeing as a result of cross-Government commitment to all sectors working together.* *Evidence-based high quality services are delivered through appropriate, cost-effective investment in mental health.*
A MORE EQUAL WALES	*People feel in more control as partners in decision-making about their treatment and how it is delivered.* *People of all ages benefit from evidence-based interventions delivered as early as possible and from improved access to psychological therapies.*
A PROSPEROUS WALES	*People and communities are more resilient and better able to deal with the stresses in everyday life and at times of crisis.* *Providers are positively managing risk, supporting people to increase their levels of hope and aspiration and enabling them to realise their full potential through recovery and enablement approaches.*
A WALES OF COHESIVE COMMUNITIES	*People of all ages and communities in Wales are effectively engaged in the planning delivery and evaluation of their local mental health services.* *Inspirational leadership and a well-trained, competent workforce in sufficient numbers ensure a culture which is safe, therapeutic, respectful and empowering.*

2.1.1 The Social Services and Well-being Act (Wales) 2014 and the accompanying Welsh Government 'National Outcomes Framework' is the legislative context within which the

study sits, and is driving change for all aspects of social services and social care practice across Wales, including for third sector organisations commissioned by the public sector. The National Outcomes Framework is also relevant, with linkages between area of policy and the potential impacts of the Mental Health Social Prescribing study.

2.1.2 Together for Mental Health is the Welsh Government strategy which sets out its ambitions for improving mental health and improving the well-being of people in Wales. The accompanying Delivery Plan: 2016-19 identified 11 priority areas with a series of goals underpinning them.

2.1.3 Strategy for Older People in Wales 2013-2023 also has much relevance to the study. The delivery action plan concentrates on the three priorities for the Strategy for Older People, having a sense of purpose and good relationships (1), living in a community that is sensitive to a person's needs (2) and affording a good quality of life (3).

2.1.4 A Healthier Wales: our Plan for Health and Social Care has brought together a number of these policy areas and is the Welsh Government's response to the Parliamentary Review of Health and Social Care in Wales. The proposed whole system values are an important context for this study:

- Co-ordinating health and social care services seamlessly
- Measuring the health and wellbeing outcomes which matter to people
- Proactively supporting people throughout the whole of their lives, and the whole of Wales
- Driving transformative change through strong leadership and clear decision making, adopting good practice and new models nationally
- Promoting the distinctive values and culture of the Welsh whole system approach with pride

In addition to this national context, there is much relevant information to be gleaned from the local population assessments, and emerging local area plans. This information will be triangulated with the regional priorities of the GP clusters, health boards, local authorities, Public Service Boards and the Regional Partnership Boards.

3.0 AIMS, OBJECTIVES AND RESEARCH QUESTIONS

3.1 PRIMARY AIM

To evaluate the social prescribing service's impact on individual and system-level outcomes, compared to usual care.

3.2 PRIMARY OBJECTIVES

To assess the ways in which the model is achieving the individual-level outcomes as identified by people who have been engaged in the Mind Cymru service with a link worker around:

- Well-being, quality of life and loneliness;
- Their use of non-clinical community services and primary care services;
- The extent to which their individual outcome scores change over time in response to being listened to by people who are responsible for providing services to assist them; and
- Having their health and social care problems solved quickly and holistically.

3.3 SECONDARY OBJECTIVES

To reflect on system-level outcomes of the evaluated sites, drawn from health and social care system metrics, such as, waiting times, prescription rates, repeat appointments, non-attendance rates, confidence of health and social care professionals in this model and the voluntary sector to deliver it.

3.4 RESEARCH QUESTIONS

Data will be collected in order to answer the following key study questions:

- To what extent does the intervention have on individual outcomes (e.g. well-being, quality of life and loneliness) over time?
- How well-suited was the response of the social prescribing model to the needs of the individual?
- To what extent does delaying delivery of the service make a difference to individual outcomes (e.g. well-being, quality of life and loneliness)?
- Why and when do some individuals partially complete or not complete the social prescription?
- What lessons can be learned about the optimum service delivery model for such services?
- What are the resources deployed in delivering a social prescribing service and the related costs?
- What are the economic consequences of the social prescribing service (as assessed by quality-adjusted life years (QALYs), for example)?

- To what extent is there impact on NHS resources (e.g. primary healthcare visits, prescription rates) of the social prescribing intervention?
- To what extent are there implications for policy and strategy both locally, regionally and nationally?

4.0 OUTCOMES

4.1 RECOVERING QUALITY OF LIFE (REQOL)

ReQoL (Keetharuth *et al.*, 2018) is a patient reported outcome measure that assesses the quality of life of people with different mental health conditions. The ReQoL measure that will be used in this study contains 20 mental health items. It also contains one physical health question. This tool was chosen due to its sensitivity to mental health outcomes.

This tool may also allow for the study to draw conclusions regarding the cost consequences of its work expressed in terms of Quality Adjusted Life Years, or QALYs. Welsh Government have commissioned a Welsh translation of ReQoL, which they anticipate will be ready in June/July 2019 for use in this study.

4.2 SHORT WARWICK EDINBURGH MENTAL WELL-BEING SURVEY (SWEMWBS, 7 DIMENSIONS)

SWEMWBS is a shortened version of the Warwick Edinburgh Mental Well-being Survey (WEMWBS; Tennant *et al*., 2007) which is a 7 item measure of mental well-being (Fat, Scholes, Boniface, Mindell & Stewart-Brown, 2017). The shortened version of the tool is being used to reduce burden on participants.

4.3 UCLA LONELINESS SCALE (VERSION 3)

The UCLA-3 Loneliness Scale comprises 3 questions that measure three dimensions of loneliness: relational connectedness, social connectedness and self-perceived isolation.

4.4 SERVICE USE

Service usage will be collected from participants through self-report measures. These include:

- Number of contacts with primary care services, community services or emergency services in the 6 months prior to starting the service.
- Number of contacts with primary care services, community services or emergency services in the 6 months after starting the service.
- Prescriptions for medication for anxiety or depression and changes in prescription since the first appointment with the link worker.

This data will be collecting using case report forms.

4.5 REFERRAL AGENCIES (LOCAL MIND ORGANISATIONS)

Data on referral agencies includes:

- Type of organisation being referred to into the community.
- The number of times the patient has attended the type of organisation in the community since receiving the first link worker referral.
- Numbers of employed patient facing staff (FTE) working on project
- Number of working weeks per annum
- Weekly working hours of patient facing staff

- Time spent (hours) by patient facing staff on the following activities for each individual patient
    - Face to face meetings with client (time to include travel time)
    - Telephone conversation with clients
    - Other patient focussed work for each patient
- Some idea of time inputs from volunteer staff on individual patients or a rough estimate of the average time input from volunteer staff to each patient
- Number of visits made to each patient by (a) staff and (b) volunteers

4.6 COST DATA

- Total expenditure on direct service delivery from working on the project
- Travel expenses associated with client visits (staff and volunteers)
- Other organisational overhead costs attributable to the project (including a proportion of all elements of organisational cost.

4.7 QUALITATIVE INTERVIEW WITH PARTICIPANTS

- Face to face or telephone interviews with individuals who have taken part/are currently taking in the trial and received/receiving the social prescribing intervention.
- Some participants will be invited to participate in a single one-off interview, whereas some will be invited to participate at a maximum of three time points to capture experience at different stages.
- An interview schedule which addresses topics including; experience of the intervention, experience of social prescribing referrals, impact of the intervention, challenges experienced, will be used. A copy of the interview schedule is included in this application.
- Note: These interviews will only take place with new participants who are recruited following ethical approval. Participants who are already taking part in the study will not be invited to participate.

5.0 STUDY DESIGN

5.1 INTRODUCTION TO STUDY DESIGN

This study will employ a mixed methods design, using a co-productive participatory approach, which includes a randomised waitlist trial design (see Figure 1 for the flow chart) and realist qualitative methods. The study has been co-designed with the research team at USW, Mind Cymru, the link workers, Primary Care teams working within the study sites and the PRIME SUPER group

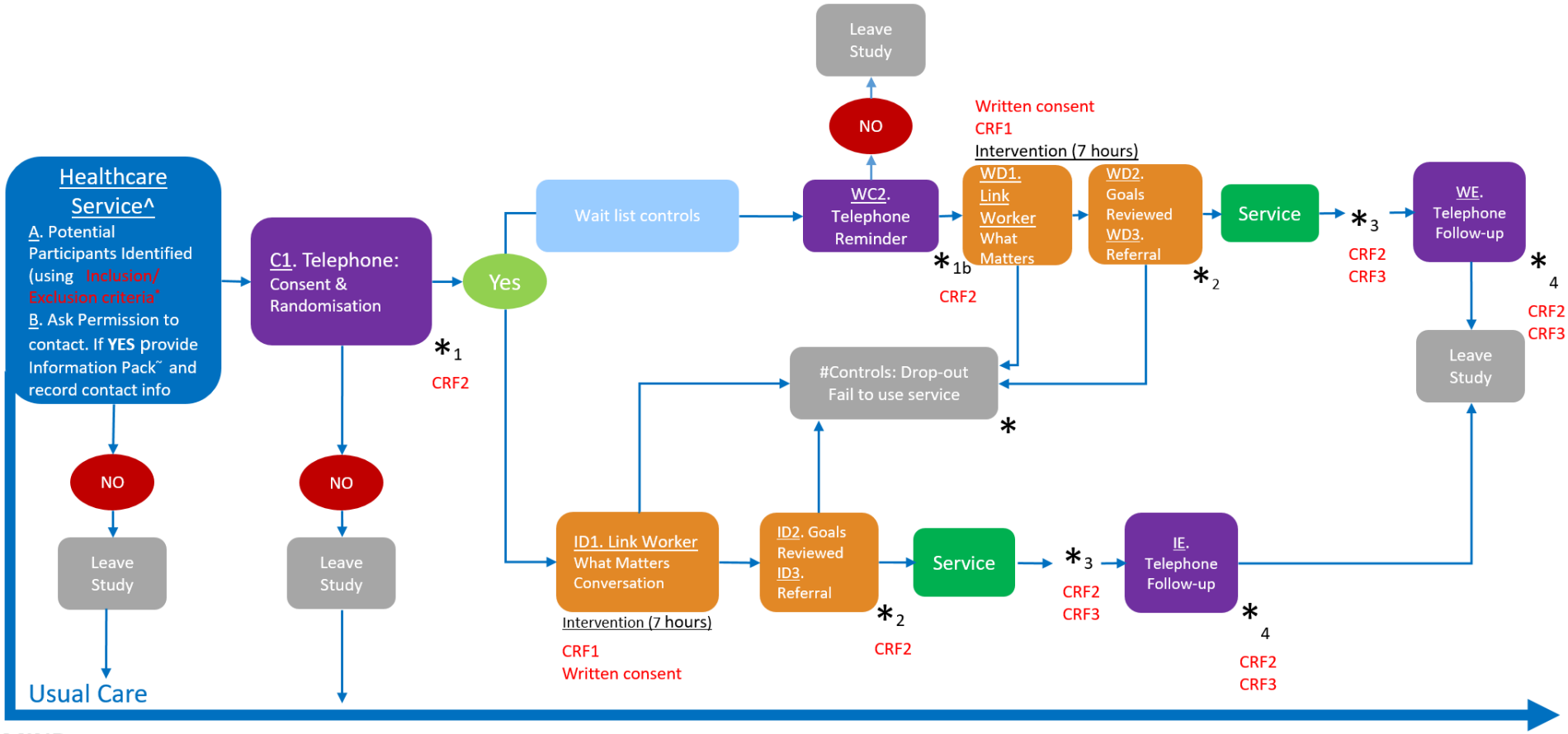
The study will assess the effectiveness of services provided through making three sets of comparisons (based on a set of individual- and service-level outcomes; see Section 4.0) over time – essentially comparing between:

- The four Local Mind sites (Merthyr and Valleys, Vale of Clwyd, Brecon and District, Ystradgynlais);
- Those who complete the intervention immediately, with those who are in the waitlist group;
- Those who fully complete the social prescribing intervention with those who do not complete or partially the full social prescription but receive care as usual (either because they do not attend or only partially attend)

5.2 RANDOMISATION PROCESS FOR THE WAITLIST TRIAL

Upon receiving verbal consent to join the study, the participant will be randomised into one of two groups (Point C, Fig 1). Group 1 will receive an appointment to see the Mind link-worker within 5 to 10 working days (with a target of 5 days). While those randomised to Group 2 will receive an appointment to see the Mind link-worker 25 (or more) working days later (5 + 20 days, Fig 1).

The study will use a commercial distance randomisation provider, which randomises the participant to either the waitlist (W) or immediate (I) arm of the study.



MIND Phase One Study plan

* Data collection: 1,3, 4 & 5 = Telephone link worker/Mind Cymru, 2 = Face-to-face with link worker

˜ Information Pack to contain: PIS, Consent form, MIND Info, copies of outcome tools

^ Professional Pack to contain: Patient information pack, flowchart, checklist, GP Info.

Figure 1. SPRING Study flow chart for the waitlist trial.

5.3 DATA COLLECTION METHODS

5.3.1 DATA COLLECTION – WAITLIST TRIAL

Data in the waitlist trial will be collected at four time points (*) (Table 3 and Figure 1). This process will be administered in partnership between WIHSC and the Mind Cymru project teams.

Table 3. Data collection points corresponding to the flow chart

SECTIONS	*	ACTIVITY	IMMEDIATE (I) INTERVENTION GROUP	WAITLIST (W) INTERVENTION GROUP
A & B		Referral from healthcare service (Section 6.1.1)	0 days	0 days
C1	1	Over phone with link workers, collect consent & baseline data (telephone)	+2 working days	+2 working days
WC2	1b	Waitlist only (telephone)	N/A	+20 working days
WD3 & ID3	2	After the what matters conversation & goal setting (face-to-face)	After participant finishes intervention (up to 20 working days after ID1/WD1 or less if participant finishes the service within this time).	
	3	Post service data collection (telephone/face-to-face)	+20 working days	+20 working days
IE & WE	4	Follow-up data (telephone)	+60 working days	+60 working days
		Total	82 working days Approx 4.5 months	102 working days Approx 5.5 months

Data will be collected by the Mind link workers in every instance, except for data collection point *4. This data collection will be done by Mind Cymru staff.

In addition to the outcome measures discussed in Section 4.0, participants will be asked demographic questions and questions about their daily life, general health and use of healthcare services. These questions can be found in the clinical report forms (CRF 1, 2 and 3).

CRF 1 will be used in the first data collection point (ID1 and WD1). CRF 2 will be used at the first data collection point with CRF1, as well as at all subsequent data collection which excludes the demographic questions. CRF3 will be used with CRF2 in the post service follow-up sessions (IE3/4, WE3/4).

5.3.2 DATA COLLECTION – PARTICIPANT INTERVIEWS

In addition to the waitlist trial, some participants will be invited to participate in semi-structured interviews to further explore their experience of the social prescribing intervention, any impact it may have had and challenges experienced.

Note: These interviews will only take place with new participants who are recruited following ethical approval. Participants who are already taking part in the study will not be invited to participate.

Participants will be sought at different stages of their participation in the trial:

1. After their first meeting with the link worker and the 'what matters' conversation
2. Following referral to community services
3. At follow-up (approximately 3 months after recruitment)

The rationale for this is to be able to understand the experiences, impact and challenges at different stages of the intervention.

Some participants will be invited to participate in a single one-off interview at one of the three stages listed.

Some participants recruited after the first meeting with the link worker (Point 1) will be invited to participate in interviews at the two following stages, to capture changes and developments in their experiences and progress throughout the intervention.

5.3.3 ROLES IN DATA COLLECTION

The team at USW will be responsible for preparing study materials (e.g. participant information sheet and consent form). The research team are also responsible for co-ordinating assignment of randomised participant code numbers for the waitlist trial, which are location specific. The research team will provide study-specific training for those collecting data and taking consent. The team at USW will also be responsible for contacting participants, who have given consent to be contacted, about the interviews. They will be responsible for recruiting and consenting these participants and conducting the interviews with participants.

The GPs and primary healthcare professionals within the GP surgeries will secure permission to contact from potential participants and continue to provide usual care. They will be given participant information packs as well as referrer information packs which provides them with all the information required to refer participants on to the service. They will identify eligible participants, give those participants the information packs and pass their details on to the link worker should the individual give permission to contact.

The link worker will be responsible for contacting the prospective participant two working days after their referral from the GP. They will ask participants for verbal consent and take baseline measures. They will then continue to collect data throughout delivery of the service. See the study flow chart for time points for data collection (See Figure 1).

The link workers in the Local Minds will input the data from the waitlist trial into a local spreadsheet and anonymise the data using a participant identification number (PIN). They will transfer the data to Mind Cymru who will check to see that no identifiable personal information is included and subsequently pass the data on to the research team at USW. This process will be managed by the Senior Project Officer at Mind Cymru.

5.4 DATA ANALYSIS

5.4.1 DATA ANALYSIS – WAITLIST TRIAL

Simple descriptive statistics will be used to define the collected baseline and demographic measures. Comparative non-parametric statistics will be used to quantify the questionnaire and survey data. Where appropriate relational statistics will be used to define correlations

between outcomes and groups. Statistical software (SPSS V24, USA) will be used to perform the analysis with statistical significance reached when $p < 0.05$.

5.4.2 DATA ANALYSIS – QUALITATIVE

The interview data will be analysed using Wong and Papoutsi (2016) data analysis framework with embedded Miles and Huberman (2014) interpretative content and applied thematic analysis within NVIVO 12. The 10 step process will be conducted by two researchers (R1 & R2) as follows:

Step 1 - Read all transcripts and identify all relevant text referring to stakeholder experiences (R1 &R2).

Step 2- Make judgements about the trustworthiness. R1 & R2 make judgements by reading the data independently.

Step 3- R1 coded the transcribed data into context, mechanisms or outcomes (CMO) but does not classify them as such at this stage.

Step 4- R2 double codes 20% of the data and identifies possible CMOs as examples providing four separate concept boxes to be configured with CMOs.

Step 5- Interpretation and judgement of CMO configurations. Taking each geographical area at a time each concept box is read and re-read by R1 and CMOs are developed.

Step 6- R1 revisits the original data to find supporting data for R1 interpretations.

Step 7- R1 writes summary text for CMO configurations

Step 8- R2 revisits geographical configurations and summary text, checking whether interpretations are correct, need to be changed and that all participants who have offered their experience have been included in the summary.

Step 9- Steps 5-8 are revised to ensure all 4 concept boxes are interpreted and judgements are made about the programme theory i.e. what worked for whom in what context and to what extent.

Step 10 - All CMOs and supporting interpretations are read and triangulated using a matrix by R1 & R2 to make judgements on the overall programme theory and future recommendations.

The analysed data is presented in organised explanations of context mechanism and outcome configurations. These are expressed at first as a high level schematic mapped to the participant pathway. This is followed by the detailed CMO configurations, their detailed text and summary table. The realist evaluation loop will close when comments are received by the commissioners of this study and the Wales Social Prescribing Research Network.

6.0 STUDY SETTING

6.1 RECRUITMENT SETTING – WAITLIST TRIAL

Prospective participants within four localities will be recruited to the service and study following consultation with their GP, a healthcare professional or through the nurse triage system (see Table 4).

Table 4: Location of Local Minds, GP Clusters, corresponding health board.

LOCAL MIND	GP CLUSTER	HEALTH BOARD
Ystradgynlais	Red Kite	Powys Teaching Health Board
Brecon and District	Red Kite	Powys Teaching Health Board
Merthyr and Valleys	Taff Ely	Cwm Taf Morgannwg University Health Board
Vale of Clwyd	North Denbighshire	Betsi Cadwaladr University Health Board

Healthcare professionals will identify prospective participants based on the eligibility criteria. They will then give the prospective participant information about the service and study and ask whether they give permission for contact from Mind.

Prospective participants will then be contacted at least 2 working days later by the link workers at the Local Minds to ask whether they would like to participate in the study. They will also be given the opportunity then to ask any questions or raise any concerns they have about the study. Verbal consent will be sought to begin the study.

Following verbal consent, the link worker will collect baseline data from them and randomise them to either the waitlist or the immediate intervention group. Written, informed consent will then be received when participants attend their first appointment, which will request permission for retrospective use of data that was previously collected.

6.1.1 DIFFERENT 'TYPES' OF ACTIVITY BEING UNDERTAKEN AT EACH SITE

The Primary Care clusters have different systems for arranging appointments and treating patients. There will therefore be various routes to being referred by a healthcare professional to the Mind Cymru service and study. The effectiveness of these routes will be monitored and reviewed by Mind Cymru prior to data collection.

- Traditional GP referral following a GP consultation.
- Referral by a healthcare professional in the practice (e.g. nurse, physiotherapist)
- Referral through the Total Nurse Triage system. In this, all patient appointments are triaged by a nurse who determines the best route forward for the patient, which may not always be seeing the GP. In this case the nurse may directly refer the patient to Mind Cymru.

Where the patient does not have face-to-face contact with a healthcare professional, an information pack will be posted to them. Under these circumstances the delay between contact from the link worker will extend to 5 days, to ensure sufficient time to receive and read the information prior to consenting.

6.2 RECRUITMENT SETTING – PARTICIPANT INTERVIEWS

Participants invited to participate in interviews will be participants who have already been recruited to the waitlist trial and signed a written consent form.

Participants who initial next to the clause on the consent form which states 'I give permission for the team at my local Mind and Mind Cymru to pass my contact details to the University of South Wales researchers, who may contact me about being interviewed' may be invited to participate in interviews by the research team.

There is a personal information sharing agreement between Mind Cymru and the University of South Wales to ensure that this is done securely.

6.3 RESEARCH SETTING

Wait list trial data will be collected by the link worker either over the phone or in the venue where the intervention is delivered. The intervention and data collection will take place in either a room at the GP surgery or on Local Mind premises, depending on the cluster.

The research is multi-centred and participants will be recruited from GP surgeries within 3 Primary Care clusters (Red Kite, Taff Ely and North Denbighshire) in Wales, corresponding to 4 Local Mind organisations.

Interviews will be conducted at a location most convenient for the participant, including their home, a community venue or on the telephone. Researchers may conduct the interviews in pairs or independently. Where working independently the University of South Wales lone worker policy will be followed.

When the researcher meets the participant for the interview they will give them another copy of the PIS, answer any questions that they have, take written consent from the participant and conduct the interview.

If the interview is conducted over the phone the participant will be asked to return the signed consent form by post or e-mail prior to participating.

7.0 SAMPLE AND RECRUITMENT

7.1 ELIGIBILITY CRITERIA

These criteria are the eligibility criteria for joining the Mind Cymru social prescribing service, and therefore the study that runs alongside it.

7.1.1 INCLUSION CRITERIA

Primary care service users who are, at the point of referral:

- Experiencing mild/moderate mental health and/or emotional wellbeing disorders (e.g. anxiety or depression)
- Aged 18+ years
- Registered with a GP in Wales

7.1.2 EXCLUSION CRITERIA

Meeting the following criteria would mean that a person is not eligible to join the study.

- Unable to give written, informed consent
- Unable to answer all questions (WEMWBS and EQ-5D) at baseline
- Worsening of mental health condition to the point where more intensive support is required (link workers will assess this throughout contact time with participant, and consult with GP who made referral if they have concerns)

7.2 SAMPLING

7.2.1 WAITLIST TRIAL

The study recruitment target is 1,500 participants, randomized into two groups (a control group, n = 750 and an intervention group n = 750). The sample collected across the 3 Primary Care clusters over the 24-month period that the study is open. An attrition rate of 5% is expected. Recruitment will end after 18-months, allowing for 6 months to complete the study and follow-up on participants. The service may continue independently of the study.

The recruitment target has been chosen to define single point changes in the questionnaires (*i.e.* ReQoL, SWEMWBS and UCLA-3).

7.2.2 PARTICIPANT INTERVIEWS

Purposive sampling will be used in this study to gather a range of experiences at different stages of the intervention with a variety of participants. The recruitment target for this arm of the study is 35-40 participants. See table 5.

Table 5. Sampling strategy for the participant interviews

	After LW meeting 1	After referral to community service	Follow-up (3 months+)
Immediate	2-3 typical cases 2-3 extreme cases	2-3 typical cases 2-3 extreme cases	2-3 typical cases 2-3 extreme cases

Waitlist	2-3 typical cases 2-3 extreme cases	2-3 typical cases 2-3 extreme cases	2-3 typical cases 2-3 extreme cases
Drop out	2-3 typical cases 2-3 extreme cases		

7.3 RECRUITMENT

7.3.1 RECRUITMENT – WAITLIST TRIAL

Participants will be recruited through the routes described in Sections 6.1 and 6.1.1 (GP, HCP, triage).

These referrers will make a primary assessment about the prospective participant's suitability and eligibility for the service and study and give them an information pack about the study. The prospective participant will then be contacted by the link worker two working days later to discuss the study, answer any questions and take verbal consent if the person wishes to participate.

Participants will then be asked to return their consent forms in their first appointment. If they do not bring this consent form to their first appointment, spares will be provided. This consent form will request permission for use of data collected retrospectively over the phone.

7.3.2 RECRUITMENT – PARTICIPANT INTERVIEWS

In the written consent form that participants sign in their first meeting with the link worker there is a clause stating '*I give permission for the Mind team to pass my contact details to the University of South Wales researchers, who may contact me about being interviewed*'. If participants initial the box next to this statement, they will be flagged as a potential participant to invite to take part in an interview.

Purposive sampling will then be used in this arm of the study to identify participants within the waitlist trial, who have consented to contact for an interview, at different stages of the intervention:

1. After their first meeting with the link worker and the 'what matters' conversation
2. Following referral to community services
3. At follow-up (approximately 3 months after recruitment)

These point coincide with data collection points from the waitlist trial, from which the link workers will enter data collected onto a central, anonymised spreadsheet. Using the anonymised spreadsheet, the researchers will identify both typical and extreme cases who could be invited to participate in an interview:

- Typical cases: Refers to those who are normal or average participants, who have completed the usual process of the trial arms and as a result have specific and in-depth knowledge of certain aspects of the normal process.
- Extreme cases: Refers to those participants who have unique experiences of special characteristics (Etikan, 2016).

Once the researchers have identified the participant's they may like to interview through their anonymised PIN, they will request these participant's details from the local Mind

organisations. The USW research team will contact the participants to invite them to participate in an interview and share the Interview PIS and interview consent form with them.

The interview will be scheduled to take place at a time and location convenient to the participant or on the telephone.

7.4 CONSENT

7.4.1 CONSENT – WAITLIST TRIAL

Copies of the participant information sheet and consent form will be given as part of an information pack to the participant during their appointment with the healthcare professional. Where a participant does not meet with the healthcare professional face-to-face, an information pack will be posted to them after receiving permission to contact, and the time between referral and contact from the link worker will be extended accordingly, as discussed in Section 6.3.1.

Participants will first be asked by a staff member of the GP surgery (the GP, practice nurse, healthcare professional, receptionist) to give permission to be contacted by the link worker/Mind employee.

Participants will be given two working days after the referral to consider the information. The link worker will then contact the prospective participant and they will be given an opportunity to find out more about the study and raise any concerns they have, before joining the study. Joining the study will be confirmed by verbal consent, the participant will then be randomised into the wait control, or intervention arm. It is important that the participants are blind to the randomisation process, because those assigned into the wait control group may behave differently or feel disadvantaged if they are aware of having to wait unnecessarily to receive the service. At this point baseline demographic data will be collected and the baseline questionnaire measures. Consent to contact participants further will be sought from the wait control arm participants and from those who fail to attend link worker appointments or drop-out of the study.

Written, informed consent will then be received during the first consultation with the link worker. This will allow the data collected with verbal consent to be used in the study along with any further data collected.

7.4.2 CONSENT – QUALITATIVE

The amended consent form (Version 3, October 2019) includes a clause: '*I give permission for the team working in my local Mind and Mind Cymru to pass my contact details to the University of South Wales researchers, who may contact me about being interviewed*'.

Participants who initial the box next to this statement will be noted as giving permission for their details to be passed to the research team.

The research team will contact these individuals and invite them to participate in an interview. If the participant agrees they will be given another PIS (PIS-Interview) with more information about the study, this will be shared with them by post or e-mail prior to the interview.

Before the interview, the participant will have the opportunity to ask the researcher any questions and will be asked to sign a consent form for the interview (Consent-Interview).

8.0 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 ASSESSMENT AND MANAGEMENT OF RISK

The study-specific risks for the participants are low.

A potential risk is the 20 working day delay in receiving the intervention in the wait list control arm. This risk is minimised by the participants continuing to receive usual care from their GP surgery throughout the study (Figure 1). Furthermore, this risk is also minimised by the inclusion criteria limiting the sample to participants with mild-moderate mental health issues and excluding those with more complex or severe needs.

A potential risk for participants taking part in the interviews is discussion of potentially sensitive topics. Participants will be made aware that they can pause or terminate the interview at any point if they wish to. The research team will also provide referral to support where appropriate for the participant.

Other risks: The study asks the participants to complete the questionnaires and data collection on four or five occasions, and they may become sensitised to answering the questions. If this occurs the link worker will note any distress and note the shortfalls in data collection, the participants will continue in the study if they so wish.

Mind Cymru will oversee that inappropriate referrals are discouraged and prevented, that it is appropriate to contact the participant and to report to the study team if any participants cannot continue with the study. Referral to the participant's GP will mitigate against these risks.

Where researchers are undertaking interviews alone they will follow the University of South Wales lone worker policy.

Some participants will be invited to participate in multiple interviews at varying stages of the intervention. The repeated interviews may become burdensome for participants. If this occurs participants will be made aware that they can withdraw at any time. To mitigate the risk of this, interviews will be held at a time and a place convenient to the participant, or over the phone.

8.2 RESEARCH ETHICS COMMITTEE (LREC) AND OTHER REGULATORY REVIEW AND REPORTS

This design has been reviewed by multiple agencies through the bidding process, including Mind Cymru, link workers, commissioning groups (Welsh Government).

This study has been co-designed in partnership with key stakeholders within the partner organisations, Mind Cymru as well as partners in the GP clusters, the PRIME SUPER group and the USW research team.

Version 2 of the protocol was approved by Wales Research Ethics Committee 3 and given Health Regulatory Authority/Health and Care Research Wales approval on 27.06.2019.

A non-substantial amendment was made to the protocol on 25.07.2019 and approved by Wales Research Ethics Committee 3.

A substantial amendment is now being applied for to Wales Research Ethics Committee 3.

8.3 PATIENT AND PUBLIC INVOLVEMENT

The study team has consulted the PRIME Centre Wales SUPER group on the waitlist trial design, this group has been convened to provide patient and public involvement and contributions in research study design.

The PRIME group assessed and considered the acceptability of the research, the design of the study, proposed management of the study, plans for undertaking the study, proposed analysis and dissemination plans.

An 89-year-old member of the public was consulted regarding the coherence and clarity of the interview schedule ahead of this amendment submission for the qualitative element of this mixed-methods design.

8.4 PROTOCOL COMPLIANCE

The Welsh Institute for Health and Social Care (WIHSC) Programme manager, Lisa Griffiths and CI, Professor Mark Llewellyn, will be responsible for monitoring protocol compliance.

8.5 DATA PROTECTION AND PATIENT CONFIDENTIALITY

All personal data will be collected and stored in accordance with GDPR (2018) regulations. There is a data sharing agreement between Mind Cymru and USW as part of the contract. There are also data sharing agreements between Mind Cymru and the Local Minds.

The local Minds will hold the site files and all personal data and contact information. They can share this information with Mind Cymru when necessary, who can share this information with the USW study team. For the data collected through the waitlist trial (quantitative data), the USW study team will hold only anonymised and codified data and act as the data custodians.

USW will receive contact information from Mind Cymru, where participants have specifically given prior consent to this sharing of information. This is so that the USW research team can contact participants to invite them to interview and conduct some repeated interviews over time. Data collected through interviews will be anonymised at the point of data collection and stored securely.

Information will not be stored or processed on personally owned devices or email accounts. Data will be backed up securely on a weekly basis as a minimum, and we will not use Cloud storage services. All information will be encrypted in transit using services such as PGP or Egress Switch when emailing.

The University of South Wales research team will have full access to the final dataset, and data will be destroyed after 5 years of study closure.

8.6 INDEMNITY

The University of South Wales are the study sponsors and liaise with the three NHS Health Boards on the terms and conditions.

Cwm Taf Morgannwg UHB will be the Lead NHS R&D Site.

9.0 DISSEMINATION POLICY

All the SPRING study data will be owned and returned to the funder, Welsh Government.

The final SPRING study findings will be incorporated into an overall report detailing the findings of the commissioned work, produced by the research team at University of South Wales in collaboration with the study partner, Mind Cymru. This will be submitted to Welsh Government. The Welsh Government will determine the report access.

The study team will seek permission to publish peer reviewed articles and develop conference presentations for local conferences and mental health conferences, from the data owned and returned to the funder that is collected as part of the study.

Study reports will be published on the Mind Cymru website for participant access, with permission from the funder.

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