The Impact of Social Prescribing on Mental Health: A Protocol for Two Randomised Wait-List Controlled Feasibility Studies, Social Prescribing in Mental Health Study (SPRING) and Mental Health Through Social Prescribing Project (PROSPECT)

Megan Elliott (megan.elliott@southwales.ac.uk)
University of South Wales Faculty of Life Sciences and Education
https://orcid.org/0000-0001-6495-5576

Mark Llewellyn
University of South Wales - Trefforest Campus: University of South Wales

Carolyn Wallace
University of South Wales - Trefforest Campus: University of South Wales

Sarah Wallace
University of South Wales - Trefforest Campus: University of South Wales

E Mark Williams
University of South Wales - Trefforest Campus: University of South Wales

Study Protocol

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Abstract

Background

Social prescribing aims to connect citizens with sources of support in their communities to benefit their health and well-being. Despite its ongoing implementation within the United Kingdom, the evidence base for social prescribing has been criticised, citing a lack of rigour, high risk of bias and inconclusive findings to date.

Methods

This study protocol aims to examine the feasibility of using large, randomised control studies to assess the mental health and well-being impacts of social prescribing. Two wait-list control studies, each consisting of two parallel arm groups, SPRING and PROPSECT were designed. Participants were referred via their consulting healthcare professionals. The participants were randomised to receive the intervention immediately or after a delay of four weeks. The intervention in the SPRING study was a personal “what-matters” interview by a Link Worker consultation leading to a prescribed social service. Three month and six month follow up of service use was proposed. In PROPSECT, the intervention was a holistic social prescribing service. In both trials the primary outcomes were quality of life, service uptake, and participant experience.

Discussion

Social prescribing is becoming popular in community health and care services. It is believed to be an effective resource, and this is first randomised control trial to attempt to demonstrate the effectiveness of social prescribing for people with Mental Health and/or emotional well-being issues. A waiting-list control study is feasible in this context but would be suitable for larger randomised controlled trials.

Trial Registration: SPRING, Clinical Trials, NCT04062903. Registered 17th September 2019, https://clinicaltrials.gov/ct2/show/NCT04062903?term=NCT04062903&draw=2&rank=1. PROSPECT, Clinical Trials, NCT04099095. Registered 23rd September 2019, https://clinicaltrials.gov/ct2/show/NCT04099095?term=NCT04099095&draw=2&rank=1

Introduction

Background and Rationale

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 [1]. In Wales, social prescribing has many models which require the NHS and third sector organisations to work closely together. Models of social prescribing vary widely, ranging from ‘light touch’ signposting services through to holistic services, in which the social prescription is co-developed and sustained over a period of time by the individual and the link worker [2].

These involve referral to a link worker/community connector/social prescriber/link co-ordinator from primary care or another referral route, such as social work or housing [3]. These roles, referred to hereafter as link workers, 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 [4]. However, there is limited research evidence to judge its effectiveness, who benefits (if at all) and its value for money [5, 6]. Systematic reviews of the social prescribing evidence base have highlighted a high risk of bias and lack of rigorous evaluation to date [5, 7]. 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 [8]. Evaluations of social prescribing are predominantly descriptive, rarely involve a comparison or control group and utilise small sample sizes [5, 9]. Mixed-method and quantitative studies undertaken to date have largely employed pre-post-test uncontrolled methodologies, with a high risk of bias [5, 9]. Despite this, utility of randomised controlled trials as a means of evaluating social prescribing is contentious, given the potential ethical and moral implications of precluding patients from accessing services in the community which may improve their health and well-being [10]. The value of mixed-methods research in social prescribing is evident, particularly where a sequential design permits further exploration of findings to understand underlying mechanisms [10–12].

It is therefore important to employ rigorous, yet ethical, methods to evaluate social prescribing interventions in the community. Integration of mixed-methods and generating data from multiple sources is also crucial in evaluating social prescribing to capture a cohesive
understanding of the impact of social prescribing [11]. This protocol describes a mixed-methods, randomised wait-list controlled trial feasibility study design, to evaluate two Welsh Government (WG) funded, third sector social prescribing pilots in Wales focused on people (18+) with low to moderate mental health and emotional well-being problems. Shortly after the trial opening, it was closed due to COVID-19 pandemic, which led to all non-COVID-19 research in Wales being suspended.

Within the wait-list trial participants were to be randomised to receive the service immediately or wait for 20 working days (control) before receiving the intervention. This design provides a participant control group along with a matched intervention group, which allows all participants to receive the intervention. In addition, all participants continue to receive usual care from their General Practitioner (GP). Both quantitative and qualitative data were to be collected at determined time points in the trial pathway and integrated to draw conclusions regarding efficacy and impact of the social prescribing interventions.

**Study Objectives**

The primary objective of SPRING and PROSPECT was to demonstrate the feasibility of using a randomised wait-list controlled study to assess the effectiveness of social prescribing for people with low to moderate mental health and/or emotional well-being problems seeking support through their local primary care provider. The secondary objective was to define the impact social prescribing consultation had on the uptake and use of community services pertinent to managing personal mental health and well-being.

**Methods**

**Study Context**

The Welsh Government (WG) funded two third sector organisations, Mind Cymru and British Red Cross to deliver two social prescribing pilots in multiple localities of Wales [4]. Both services were designed to provide support for individuals with low to moderate mental health problems. The Mind Cymru project involved link workers providing tailored support plans and supporting engagement with community services for individuals who are isolated, lonely and at risk of poor mental health. The British Red Cross project involved a social prescribing model in which individuals worked with link co-ordinators (link workers) over a period of 8–12 weeks, to co-produce goals which aimed to empower them to develop non-clinical responses to managing their mental distress. Both organisations commissioned the same research group to conduct an independent trial of their pilot.

**Study Design**

The two feasibility studies, SPRING (Mind Cymru) and PROSPECT (BRC) were designed as two-arm, parallel group, randomised wait-list trials to explore the benefits of social prescribing on mental health and/or emotional well-being (Table 1). Both studies began recruiting in Oct 2019 but were closed prematurely due to contact restrictions imposed by the COVID-19 pandemic. When the study opened participants were invited to join the study if they had consulted their healthcare provider seeking advice on mental health and/or emotional well-being issues and were considered suitable by their healthcare provider to receive treatment from the third sector organisations.
Table 1
Aims for SPRING and PROSPECT trials

| Research 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? |

In each study, 50% of participants were to be randomly assigned to arm one, which offered an appointment to start the social prescribing intervention immediately, or arm two, which offered a first appointment 20 working days in the future (wait-list control).

Setting

SPRING and PROSPECT were set to be delivered in multiple health board localities in Wales. These included areas of deprivation and rural communities within the Betsi Cadwaladr University Health Board, Cwm Taf Morgannwg University Health Board and Powys Teaching Health Board for SPRING (n = 4 localities), and Aneurin Bevan University Health Board and Hywel Dda University Health Board for PROSPECT (n = 2 localities). The intervention was to be delivered at the local organisation base or within GP surgeries. Recruitment was directed within the healthcare service, through local GPs.

Inclusion and exclusion criteria

Individuals were eligible to participate if they were experiencing mild-moderate mental health, and/or emotional wellbeing disorders (e.g. anxiety or depression), aged over 18 years and registered with a GP in Wales.

Participants were excluded and not eligible to join either study if they were i) unable to provide written, informed consent, ii) unable to answer all survey questions (see Table 2) at baseline, and iii) once recruited to the study if their mental health condition deteriorated to the point where more intensive support was required.

Intervention

The intervention was provided by the link workers employed by Mind Cymru or British Red Cross. For the SPRING study (Mind Cymru), the intervention consisted of a “What Matters conversation” and a referral recommendation to a suitable local social service. The Mind Cymru approach was to deliver what might be defined as a ‘signposting’ model of support. Their original intention was to work with around 1500 participants to understand their needs and then work with community assets and resources to support the person. For British Red Cross, their model was more of a holistic, intensive approach. They were aiming to support around 200 people in the same time period as Mind Cymru, but to work for longer time periods (8–12 weeks) with people on a one-to-one-basis. They also worked with resources within the community, but maintained a more direct relationship with people for a longer period.

Control condition

A wait-list control group was used as it was not possible to withhold support from participants. Random allocation to the control group occurred after baseline assessment (Fig. 1, Table 2). This wait period was deemed long enough (20 + working days) to assess the effect of registering onto the service compared to receiving the service directly. An extra control group was established via consent to follow-up participants who chose not to receive the social prescription following the link worker contact in the SPRING study (self-selected controls).

Endpoints
With SPRING and PROSPECT being feasibility studies, the endpoint was considered the successful collection of the outcome measures and tools data at the last follow up period. Full recruitment (100%) would have indicated a full trial, but a lower recruitment rate would allow conclusions to be made on the feasibility of using a wait-list design with randomised allocation to provide an intervention free period.

Participants’ timeline in study

Once referred to the study, within one calendar week (with a 2-day target) participants were contacted by telephone and asked to confirm that they wished to join the study. Those in the intervention arm were then given an appointment to talk with the link worker. Those in SPRING went on to receive a social intervention and followed up at 1 and 3 months, whereas in PROSPECT after the first interaction with the link worker, a follow-up was planned at the intervention end and 3-month later (Fig. 1, Table 2). Those allocated to the control arm followed the same timeline with the ‘wait’ period inserted between the baseline assessment and meeting the link worker.

Table 2. Schedule of recruitment, intervention and assessment for SPRING and PROSPECT

| Study Period          | Recruitment | Allocation | Post-allocation | Close |
|-----------------------|-------------|------------|-----------------|-------|
| Timepoint             | T1 Baseline | T2         | T3              |       |
| Recruitment           | X           |            |                 |       |
| Eligibility Screen    | X           |            |                 |       |
| Informed Consent      | X           |            |                 |       |
| Allocation            | X           |            |                 |       |
| Wait-list             | X           |            |                 |       |
| Interventions         |             |            |                 |       |
| SPRING What Matters Conversation | X           |            |                 |       |
| SPRING Goal Review    |             |            | X               |       |
| PROSPECT Core Support |             |            |                 | X     |
| Assessments           |             |            |                 |       |
| Demographic data (Age, Gender, Health Status, Recent visits to GP) | X           |            |                 |       |
| Recruitment Rate      |             |            |                 |       |
| Measures (ReQoL-20, SWEMWBS, UCLA-3, WEMWBS, EQ-5D-5L) | X           | X           | X           |       |
| Interviews with participants |             | X           | X           | X           |       |
| Monitoring of adverse events |             |             |                 |       |
| Monitoring of delivery of intervention |             |             |                 |       |

Sample size

Sample size for the two feasibility studies was determined pragmatically and although consideration was given to powering the study by differentiation of questionnaire scores, a pragmatic decision (based on time available) was made to limit the SPRING study to 1500 and up to 200 for PROSPECT study.
Allocation and blinding

The SPRING study used a commercial distance randomisation provider (www.sealedenvelope.com) and PROSPECT used a manual sealed envelope randomisation process, prepared by the authors. The research team were blind to the randomisation, but not the link workers who allocated each participant according to the randomisation scheme used. Participants were blind to their allocation, and those assigned to be wait-listed for their first meeting with the link worker were given a later appointment date. The participant information provided stated that appointments would be given within a month of joining the study; no mention of randomisation to either arm was mentioned.

Recruitment

Prospective participants within four localities for SPRING and two localities for PROSPECT were to be recruited to the study following consultation with a health professional (GP, nurse, practice manager). The healthcare professional was to provide the prospective participant with study information and requested permission for contact by telephone from the social prescribing service. Those who consented to contact were then to be telephoned by the link worker at least two working days later to ask whether they would like to participate. Following verbal consent, the link worker would collect baseline data (Fig. 1, Table 2–3) and randomise them. Written consent was to be subsequently collected at the first face-to-face appointment and requested permission for use of data collected retrospectively.

Data collection

Quantitative data

Quantitative data for the SPRING study was to be taken at baseline, at the end of the intervention, 1 month follow-up and 3-month follow-up. For the PROSPECT study, outcome measures were to be taken at baseline, at the intervention end (up to 12 weeks after intervention) and at 3-month follow-up. For the wait-list group, an additional data collection point was added, following the 20-working day wait, prior to starting the intervention. A clinical report form was to be generated using the outcome measures detailed below, in addition to the collection of demographic information.

Measures

Quality of life was to be recorded using the patient reported outcome measure, Recovering Quality of Life-20 (ReQoL-20) [13]. ReQoL-20 measures responses to 20 mental health items and 1 physical health item on a 0–4 scale (none of the time – most or all of the time) based on experiences of the past week. The tool was selected due to its sensitivity to mental health outcomes. It also enables assessment of Quality Adjusted Life Years (QALYs) which could be used for health economic assessments.

Warwick Edinburgh Mental Well-being Scale (WEMWBS) assesses mental well-being over the past two weeks using 14 items regarding feelings and thoughts, ranging from 0–4 (none of the time – all of the time) [14]. A short version of the WEMWBS consists of 7 items (SWEMWBS) [15]. WEMWBS is the most commonly used tool for social prescribing evaluation [16].

The UCLA Loneliness Scale comprises three questions that measure three dimensions of loneliness; relational connectedness, social connectedness and self-perceived isolation on a 1–3 scale (Hardly ever, some of the time, often) [17].

Euroqol 5D-5L (EQ-5D-5L) is a generic health index comprising of 5-items assessing mobility, self-care, usual activities, pain/discomfort and anxiety/depression, measured on a 5-point scale (No problems – severe problems) [18]. EQ-5D-5L also includes a visual analogue scale asking individuals to rate their health today on a scale from 0-100. EQ-5D-5L also enables calculations of QALYs.

Data on activity and service usage was collected through self-reported measures assessing number of contacts with primary care services, community services or emergency services in the 6 months prior to starting the service and the 6 months after starting the service. Participants were also asked to self-report prescriptions for medication for anxiety or depression and changes in prescription since first appointment.

Outcome tools employed for SPRING and PROSPECT were determined based on the service aims. Therefore, SPRING utilised a combination of ReQoL-20, SWEMWBS and the UCLA Loneliness scale, and PROSPECT utilised a combination of the WEMWBS and EQ-5D-5L (Table 3). Both studies were designed to capture self-reported information regarding service usage.
Table 3
Summary of outcome measures

| Instrument Name | Domain               | Measured | Study       |
|-----------------|----------------------|----------|-------------|
| REQOL           | Quality of Life      |          | SP          |
| WEMWBS, 14      | Mental Well-being    |          | PR          |
| SWEMWBS, 7      | Mental Well-Being    |          | SP          |
| UCLA LS3        | Loneliness           |          | SP          |
| EQ-5D-5L        | General health       |          | PR          |

Qualitative data

Some participants were to be recruited to take part in face-to-face or telephone semi-structured interviews to further explore their experiences of the social prescribing intervention, any impact it may have had, and challenges experienced.

In the initial consent form, participants were able to express an interest in taking part in subsequent interviews about their experiences. Purposive sampling was then used to gather a range of experiences at different stages of the intervention [19]. The researchers employed a sequential design to identify typical (normal or average participants) and extreme (participants who have unique experiences or special characteristics) using quantitative data collected [20]. Both typical and extreme cases were to be identified at 3 time-points; after the first link worker meeting, after referral to the community service and at follow-up. Participants were to be recruited from both study arms (immediate and wait-list), from a drop-out group, and individuals who did not engage with the service.

Participants were to be either invited to participate in a single interview at a specified time point, or for a maximum of three interviews at distinct time points, to capture experiences at different stages, addressing topics including experience of the intervention, experience of social prescribing referrals, impact of the intervention, and challenges experienced.

Data management

All personal data and contact information was to be held by the service organisations (Mind Cymru and British Red Cross), with the researchers only accessing anonymised and codified data. All data collection and storage complied with GDPR (2018) regulations. Data sharing agreements between the researchers were introduced. Data was to be backed up securely on a weekly basis. All information was encrypted in transit. The final dataset was to be destroyed 5 years after study closure.

Data coding and analysis

Simple descriptive statistics were to be used to define the collected baseline and demographic measures. Comparative non-parametric statistics were to be used to quantify the questionnaire and survey data. Where appropriate relational statistics were to be used to define correlations between outcomes and groups. Statistical significance was set at P value < 0.05.

The qualitative data was to be analysed using the Wong and Papoutsi (2016) data analysis framework with embedded Miles and Huberman (2014) interpretative content and applied thematic analysis within NVIVO 12 [21–22]. The analysed data was to be presented in organised explanations of context mechanism and outcome configurations (CMO). 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 would have closed when comments on the findings were received by the commissioners of this study and the Wales Social Prescribing Research Network.

Data monitoring

Adverse Events

These were monitored by the chief investigator based at the University of South Wales. Any reports were to be entered into the appropriate Adverse Event report forms contained in each site file and then reported to the chief investigator.

Ethics and dissemination

Ethics and approval
SPRING and PROSPECT trials were approved by the NHS Research Ethics Committee (REC Nos 19/WA/0151 and 19/WA/0161 respectively), the Health Research Authority (HRA) and Health Care Research Wales (HCRW) and finally by the local NHS health boards, Betsi Cadwaladr University Health Board, Cwm Taf Morgannwg University Health Board and Powys Teaching Health Board for SPRING and Aneurin Bevan University Health Board and Hywel Dda University Health Board for PROSPECT. The trials were briefly open before being suspended at the beginning of March 2020 due to the COVID-19 pandemic.

Consent

A multi-stage process was undertaken to gain participant consent. Primarily, prospective participants were to be given information regarding the study by the referring healthcare professional. This included an invitation, participant information sheet, consent form and sample copies of the outcome tools. At this stage, the referrer was to seek permission for sharing contact details and contact from the link workers. After two working days, the link worker was due to contact the prospective participant by telephone to answer questions and seek verbal consent to take part. Once verbal consent was received, randomisation and collection of baseline data were to be undertaken. Written, informed consent was to be collected during the first consultation with the link worker.

The consent form included a clause regarding contact for involvement in interviews about the study. If participants agreed to this clause, they were asked to provide additional written consent to be interviewed.

Confidentiality

All personal data was to be collected and stored in accordance with GDPR (2018) regulations. With SPRING, Mind Cymru held the site files and all personal data and contact information. University of South Wales (USW) researchers only held anonymised and codified data (participant ID provided at randomisation) and acted as the data custodians. All participant identifiable data collected by Mind Cymru was to be anonymised and coded prior to delivery to the research team. The link workers assigned a unique participation identification number to each recruit. Any anonymised data stored at USW was to be destroyed after 5 years of study closure. The same conditions applied to the PROSPECT study. No participant was to be identified in any subsequent publications or reports.

Dissemination

All study data would have been owned by, and returned to the funder, Welsh Government. The researchers would have presented findings from the feasibility studies in commissioned reports and disseminated outputs through peer-reviewed publications and conference presentations. Study reports would have been published on the Mind Cymru and British Red Cross websites for participant access, with permission from the funder. If successful, a larger multicentre trial would have been proposed.

Public Participation and Involvement (PPI)

The study team consulted with the PPI PRIME Centre Wales SUPER group [23] on the wait-list trial design, this group has been convened to provide PPI and contribute to research study design. The PRIME group assessed and considered the acceptability of the research, the design of the study, its management and plans for undertaking the study, and proposed ideas for analysis and dissemination. An 89-year-old member of the public was consulted regarding the coherence and clarity of the interview schedule for the qualitative element of this mixed-methods design.

Discussion

This protocol presents a mixed-methods wait-list trial design used for two feasibility studies. Both studies aimed to assess feasibility of this design for evaluating social prescribing interventions. The social prescribing evidence base has been criticised for small sample sizes, lack of controlled designs, diversity of outcome tools, significant loss to follow-up, low response rates and limited intervention uptake [1, 5, 7, 24]. These feasibility studies contribute to a much-needed evidence base, providing insight as to whether this design is appropriate, acceptable, and useful for social prescribing evaluation.

Given the similarities of the two social prescribing interventions under investigation, it follows that a single protocol describing the design is appropriate. This also provides a blueprint for other researchers wishing to evaluate social prescribing using similar methodologies, and highlights the applicability of this approach to varying services.

The study opened following ethical approval late in 2019 and both studies recruited participants to both arms, (immediate access and wait-list access). Research training for link workers and management staff was provided by the research team. The initial reticence of the link workers was overcome once the consenting and randomisation process was understood. In March 2020, recruitment was halted to
SPRING and PROSPECT studies following the COVID-19 pandemic and subsequently both trials were closed. No participant completed the study. The opportunity to restart the trial has not been possible due to financial restraints.

We anticipate that conclusions drawn from these feasibility studies will directly inform development of a high-quality, rigorous, large scale social prescribing evaluations. Waiting-list control trials are feasible to use in the assessment of social prescribing programmes.

**Declarations**

**Ethics Approval and consent to participate:** Ethical approval for both studies was granted from the Faculty of Life Sciences and Education Ethics sub-committee, University of South Wales. SPRING and PROSPECT trials were approved by the NHS Research Ethics Committee (REC Nos 19/WA/0151 and 19/WA/0161 respectively), the Health Research Authority (HRA) and Health Care Research Wales (HCRW). Permissions were sought from local NHS health boards, Betsi Cadwaladr University Health Board, Cwm Taf Morgannwg University Health Board and Powys Teaching Health Board for SPRING and Aneurin Bevan University Health Board and Hywel Dda University Health Board for PROSPECT.

**Consent for publication:** Not applicable.

**Availability of data and materials:** Not applicable.

**Competing Interests:** The authors declare they have no competing interests.

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**Authors contributions:** ME sought ethical approvals, conducted study set-up and prepared the protocol. ML was Chief Investigator for SPRING and PROSPECT, co-designed the study, oversaw all research activity and edited the protocol. SW sought NHS permissions following ethical approval, conducted study set-up and edited the protocol. CW co-designed the study, led on the qualitative research component and edited the protocol. MW co-designed the study, led on the quantitative research component and prepared the protocol.

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**Author Information:** ORCID Megan Elliott (0000-0001-6495-5576), Prof Mark Llewellyn (0000-0002-2723-6414), Dr Sarah Wallace (0000-0003-4374-3667), Prof Carolyn Wallace (0000-0002-3799-5748) and Prof Mark Williams (0000-0003-0034-1625).

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Figures
A wait-list control group was used as it was not possible to withhold support from participants. Random allocation to the control group occurred after baseline assessment.