PROSPECT

Mental Health through Social Prescribing Project

A Mental Health Social Prescribing trial (British Red Cross)

A collaboration between

University of South Wales

Canolfan PRIME Cymru Wales PRIME Centre

wihsc

British Red Cross

GIG CYMRU NHS WALES Bwrdd Iechyd Aneurin Bevan Health Board

GIG CYMRU NHS WALES Bwrdd Iechyd Prifysgol Hywel Dda University Health Board

Protocol Version 3

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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:
..../...../.....

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KEY STUDY CONTACTS

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STUDY SUMMARY

STUDY TITLE	A MENTAL HEALTH SOCIAL PRESCRIBING TRIAL (BRITISH RED CROSS)
Internal ref. no. (or short title)	PROSPECT
Study Design	Randomised waitlist evaluation using a co-productive participatory approach (see 5.0)
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 200 referrals with 5% attrition rate (see 7.2)
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 October 2021. Participants will be in the study for up to eight 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	£89,905.82

ROLE OF STUDY SPONSOR AND FUNDER

Welsh Government have provided the funding for this study. British Red Cross 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 British Red Cross social prescribing intervention, without further involvement of the funder. USW will work in partnership with British Red Cross 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 British Red Cross.

ROLE OF STUDY PARTNER – BRITISH RED CROSS

British Red Cross is responsible for managing the overall project. Particularly, their role will be to design, co-ordinate and deliver the social prescribing intervention, organise recruitment and contact participants to receive consent. British Red Cross 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. British Red Cross staff will be responsible for collecting follow-up data.

The USW research team have also worked with British Red Cross to co-produce and develop the study design.

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

The British Red Cross website will host a page about PROSPECT, which holds all of the information available to participants, participant information sheets, consent forms, copies of the measurements scales and contact information for British Red Cross. 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 will consult the PRIME SUPER group in March 2019.

Colleagues at British Red Cross 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, conducting the study, data analysis and interpretation, writing reports and dissemination of results.

The study has been designed co-productively in collaboration with colleagues at British Red Cross and British Red Cross 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

PROSPECT

A MENTAL HEALTH SOCIAL PRESCRIBING TRIAL (BRITISH RED CROSS)

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, British Red Cross are undertaking a research project in two localities in Wales, Caerphilly and Pembrokeshire, to create and test a model of social prescribing. As part of this initiative, a link worker will work with the individual over a 12-week period to discuss their needs, goals and future steps. A link worker helps the individual to explore extra services that may support them in improving their health, sense of wellness and independence by providing practical and emotional support.

This study will conduct an evaluation alongside the implementation and delivery of the British Red Cross social prescribing intervention, using a randomised waitlist evaluation method. Participants will either receive the social prescribing intervention within 5 days of giving consent, 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 and wellbeing, 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 project aims to do this by running an evaluation of a new social prescribing service delivered by British Red Cross in two areas in Wales. British Red Cross 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 over 12 weeks of core support. The link worker will also help them find services 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 and quality of life 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 person'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 British Red Cross 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 28 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. In the same way as above, Table 4 provides an analysis of the features of the strategy that are relevant to the work of the Mental Health Social Prescribing study.

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 British Red Cross service with a link worker around:

- Well-being and quality of life;
- 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 a 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:

- What effect does the intervention have on individual outcomes (e.g. quality of life and well-being) over time?
- How well-suited was the response of the social prescribing model to the needs of the individual?
- Does delaying delivery of the service make a difference to individual outcomes (e.g. quality of life and well-being)?
- 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 key drivers of the economic consequences of a social prescribing service (as assessed by quality of life adjusted years (EQ-5D) and cost data)?

- What are the impacts on NHS resources (e.g. primary healthcare visits, prescription rates) of the social prescribing intervention?
- What implications does this service have for policy and strategy both locally, regionally and nationally?

4.0 OUTCOMES

4.1 WARWICK EDINBURGH MENTAL WELL-BEING SURVEY (WEMWBS, 14 DIMENSIONS)

WEMWBS is a 14 item measure of mental-wellbeing, which focuses on the positive aspects of mental health (Tennant *et al*. 2007). WEMWBS has been collected as part of the National Survey for Wales since 2017, which would allow data from this study to be compared longitudinally with a matched sample of the Welsh population.

4.2 EUROQOL 5D-5L

The EuroQol (EQ-5D; Hurst, Kind, Ruta, Hunter & Stubbings, 1997) is a generic health index which comprises of a five-part questionnaire, assessing mobility, self-care, usual activities, pain/discomfort and anxiety/depression. A visual analogue scale also asks people to rate their health today on a scale between 0 and 100.

The data would be compared with established studies to analyse the cost of this intervention and the benefits. This 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. EQ-5D-5L is also available in Welsh which is useful for this study.

4.3 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.

We will also collect NHS numbers in order to facilitate a link with the SAIL database so that we can understand their health services utilisation before and after the intervention.

4.4 REFERRAL AGENCIES (BRITISH RED CROSS LINK WORKERS)

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 client

    - Face to face meetings with patient (time to include travel time)
    - Telephone conversation with patient
    - Other patient focussed work for each patient
- Some idea of time inputs from volunteer staff on individual patient 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

4.5 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.

5.0 STUDY DESIGN

5.1 INTRODUCTION TO STUDY DESIGN

This study will employ a randomised waitlist trial design with mixed methods using a co-productive participatory approach. See Figure 1 for the study flow chart. The study has been co-designed with the research team at USW, British Red Cross and the British Red Cross link workers working within the study sites.

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

- The two sites (Caerphilly and Pembrokeshire);
- Those who have additional step-down support phone calls for 8 weeks, compared with those who have out-of-hours support during the 12-week intervention period and those who do not use the extra support.
- 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); and
- Those in this study with comparable other studies that have previously been completed, including comparing our findings with national datasets available (primarily the National Survey for Wales which has been collecting mental well-being and outcomes data since 2017).

5.2 RANDOMISATION PROCESS

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 British Red Cross 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 British Red Cross link-worker 25 (or more) working days (5+ 20 days, Fig 1).

The randomisation process will use sealed envelopes given to British Red Cross link workers which will give them a PIN, which shows their group assignment (with either a W for waitlist or I for immediate). These participant numbers will be randomly generated and distributed to the link workers.

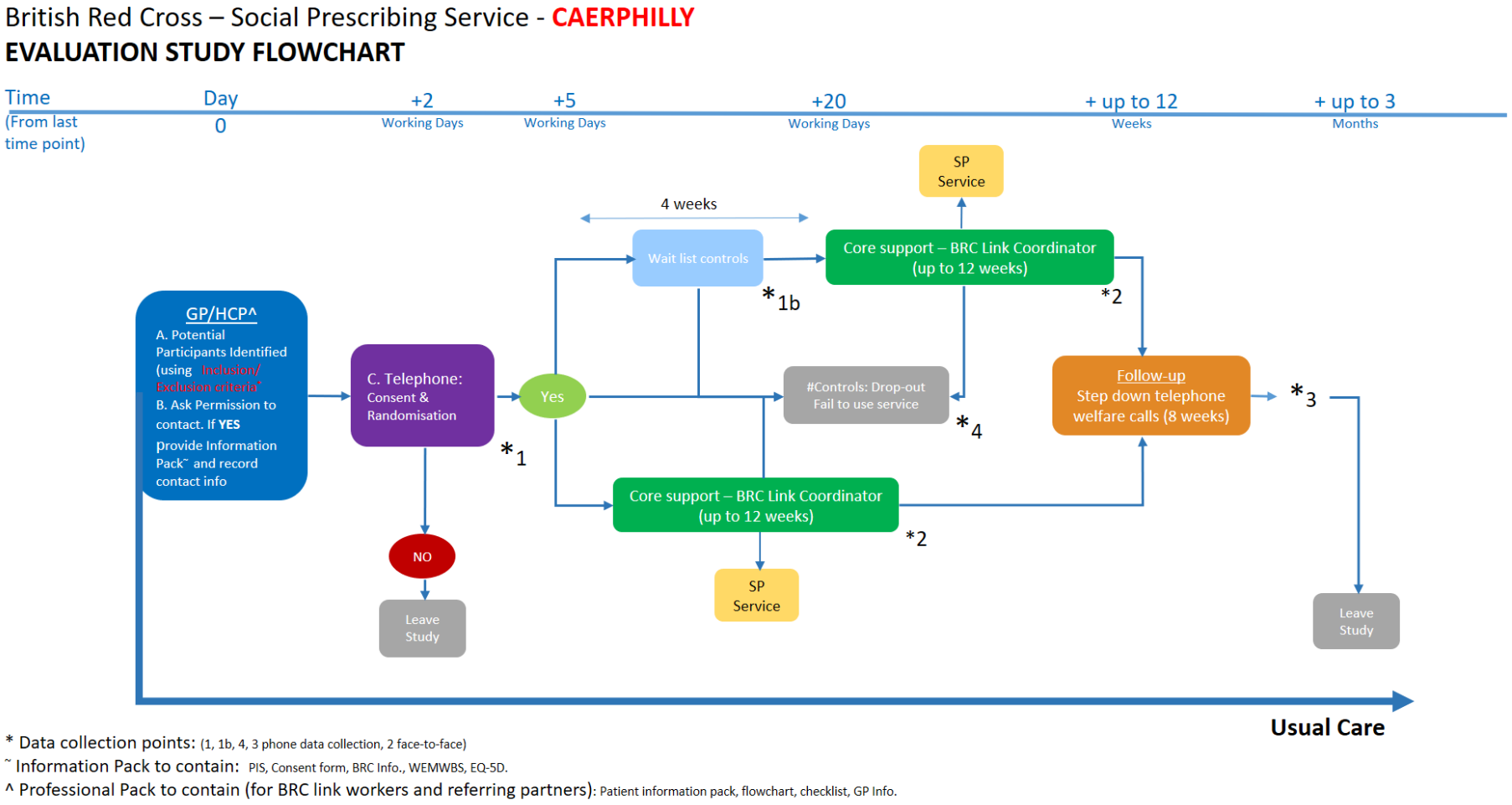

Figure 1. PROSPECT Study flow chart for Caerphilly

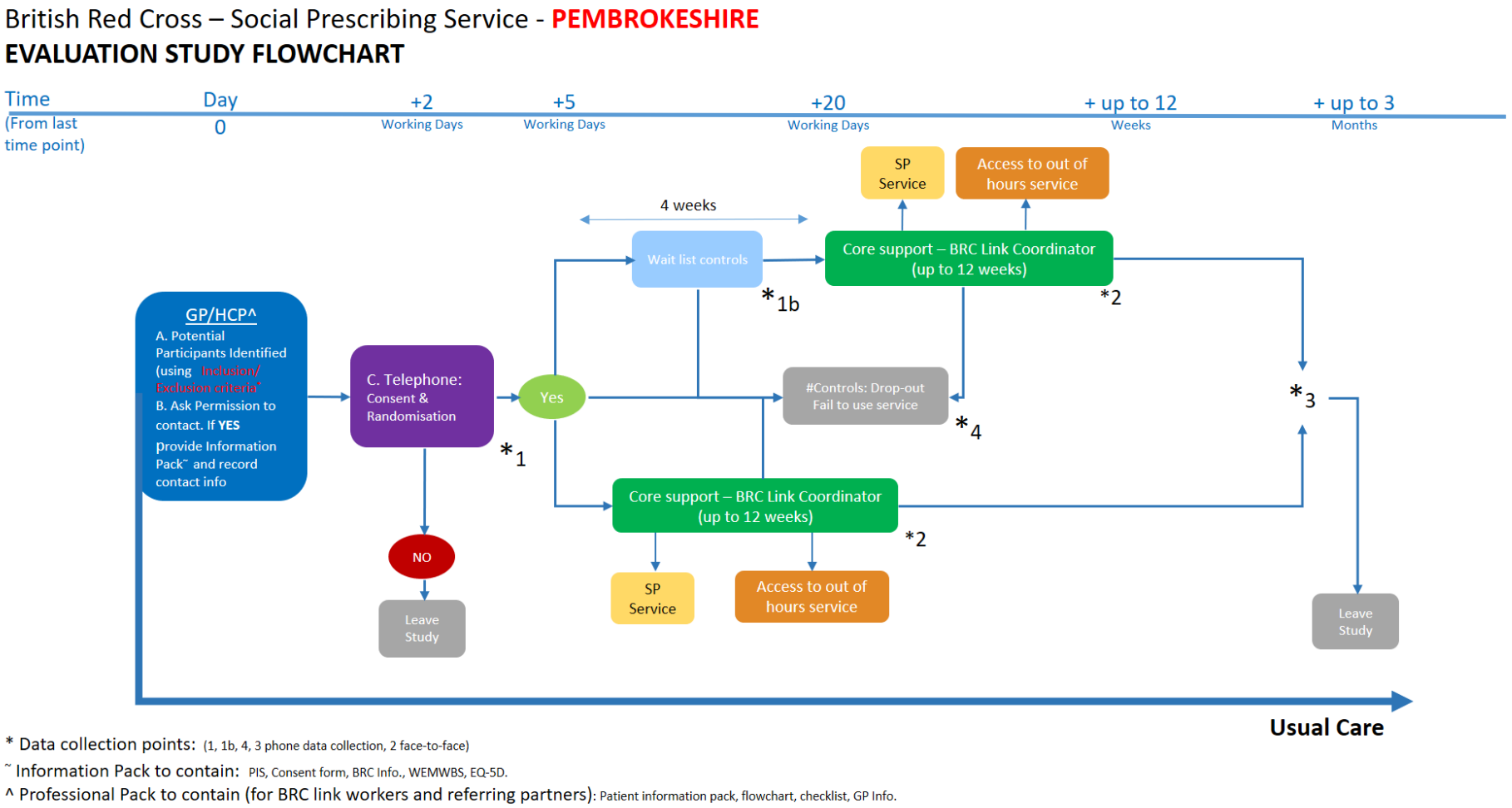

Figure 2. PROSPECT Study flow chart for Pembrokeshire

5.3 DATA COLLECTION METHODS

Data will be collected at four time points (*) (Table 1 and Figure 1). This process will be administered in partnership between WIHSC and the British Red Cross project teams.

Table 1. 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
C	1	Over phone with link workers, collect consent & baseline data (telephone)	+2 working days	+2 working days
	1b	Waitlist only (telephone)	N/A	+20 working days
Core support	2	At the end of the core support *up to 12 weeks	After participant finishes intervention (up to 12 weeks after starting the service or less if participant finishes the service within this time).	
Pembrokeshire	3	Follow-up data (telephone)	+60 working days	+60 working days
		Total	122 working days Approx 6 months	142 working days Approx 7 months

Data will be collected by the British Red Cross link workers in every instance, except for data collection point *3. This data collection will be done by British Red Cross staff.

In addition 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 case report forms (CRF 1, 2 and 3).

CRF 1 will be used in the first data collection point (*1). 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 (*2 and *3).

5.3.1 ROLES IN DATA COLLECTION

The team at USW/WIHSC 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, which are location specific. The research team will provide study-specific training for those collecting data and taking consent.

The GPs and healthcare professionals within the GP surgeries, and the Mental Health Crisis Team in Hywel Dda University Health Board, will recruit 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 need to identify eligible participants, give those participants the information packs and pass their details on to the link worker.

The link worker will be responsible for contacting the prospective participant two working days after their referral from the GP/Mental Health Crisis team. 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 will input the data into a local spreadsheet and anonymise the data using a participant identification number (PIN). They will transfer the data to British Red Cross who will check to see that no identifiable personal information is included and subsequently pass the data on to the research team at USW. British Red Cross will use Egress to ensure encryption of the data. This process will be managed by IL/CR Director for Wales at British Red Cross.

5.4 DATA ANALYSIS

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 $p < 0.05$.

6.0 STUDY SETTING

6.1 RECRUITMENT SETTING

Prospective participants within two Welsh NHS Health Boards will be recruited to the service and evaluation following a consultation with their GP or a healthcare professional in their GP surgery or through the Mental Health Crisis Team in Hywel Dda 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 British Red Cross.

Prospective participants will then be contacted at least 2 working days later by the link workers 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

There will therefore be various routes to being referred by a healthcare professional to the British Red Cross service and study. The effectiveness of these routes will be monitored and reviewed by British Red Cross prior to data collection.

- Traditional GP referral following a GP consultation.
- Referral by a healthcare professional in the practice (e.g. nurse, physiotherapist).
- Referral from a healthcare professional in the Mental Health Crisis Team in Hywel Dda University Health Board.

Where the patient does not have face-to-face contact with a healthcare professional (e.g. referral through a triage system or telephone appointment), an information pack will be posted to them. Under these circumstances the delay before contact by the link worker will extend to 5 days, to ensure sufficient time to receive and read the information prior to consenting.

6.2 RESEARCH SETTING

Data will be collected by the link worker either over the phone or where the intervention is delivered, which is decided by the participant. The intervention may be in their homes, or in a venue away from their home. As the service is about connecting people into community based services, support visits will encourage taking participants out into their community to support their involvement.

The research is multi-centred and participants will be recruited from GP surgeries within 2 University Health Boards in Wales or a Mental Health Crisis Team in Hywel Dda University

Health Board. The data collection will take place in a venue decided by the participant (home, community venue or over the phone).

7.0 SAMPLE AND RECRUITMENT

7.1 ELIGIBILITY CRITERIA

These criteria are the eligibility criteria for joining the British Red Cross 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

7.2 SAMPLING

7.2.1 SIZE OF SAMPLE

This study is an observational controlled trial and recruitment numbers for the study depend on uptake of and capacity of the British Red Cross. Based on current numbers we anticipate a study recruitment target of a minimum of 200 participants, randomized into two groups (a waitlist group, n = 100 and an immediate intervention group n = 100). The sample will be collected across 2 localities in Wales (Caerphilly and Pembrokeshire) 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.

7.3 RECRUITMENT

Prospective participants will be recruited through the routes described in Sections 6.1 and 6.1.1 (GP/HCP).

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.

7.4 CONSENT

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) or a healthcare professional in the Mental Health Crisis Team in Hywel Dda University Health Board to give permission to be contacted by the link worker.

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.

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 28 day delay in receiving the intervention in the waitlist 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.

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.

British Red Cross 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.

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 British Red Cross, link workers, commissioning groups (Welsh Government).

This study has been co-produced in partnership with key stakeholders within the partner organisation, British Red Cross and the USW research team.

This protocol was assessed by NHS Wales Research Ethics Committee (REC) 7 and Health and Care Research Wales (HCRW).

8.3 PATIENT AND PUBLIC INVOLVEMENT

The study team has consulted the PRIME Centre Wales SUPER group on the study 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.

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 data will be collected and stored in accordance with GDPR (2018) regulations. There will be a data sharing agreement between British Red Cross and USW as part of the contract.

British Red Cross will hold the site files and all personal data and contact information. The USW study team will hold only anonymised and codified data and act as the data custodians.

All participant identifiable data collected by British Red Cross will be anonymised and coded prior to delivery to the research team. The link workers will use assign a unique participation identification number to each recruit. The anonymised data will be stored securely at USW.

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. A contract between the two NHS Health Boards will signify the terms and conditions.

Aneurin Bevan UHB will be the Lead NHS R&D Site.

9.0 DISSEMINATION POLICY

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

The final PROSPECT 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, British Red Cross. This will be submitted to Welsh Government. The Welsh Government will determine where the reports can be accessed from.

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

Study reports will be published on the British Red Cross website for participant access, with permission from the funder.

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