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Impact of a community social prescribing intervention on people with type 2 diabetes living in an ethnically diverse area of high socio-economic deprivation. Exploiting a natural experiment to evaluate effects on health and health care utilisation with economic assessment and ethnographic observation

The impact of social prescribing on wellbeing, health, healthcare utilisation and costs for people with type 2 diabetes: multimethod SPRING_NE study

PROTOCOL

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2. DURATION

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3. STUDY NUMBERS

- IRAS Project ID: 238970
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4. TITLE

The impact of social prescribing on wellbeing, health, healthcare utilisation and costs for people with type 2 diabetes: multimethod SPRING_NE study

5. ACRONYM

The SPRING_NE study

6. STUDY BACKGROUND

Social prescribing enables healthcare professionals to address non-medical causes of ill-health through harnessing the resources of the community and voluntary sector in the care and treatment of patients.[1] In 2006 the Department of Health supported the introduction of social prescribing for people with long-term conditions [2] and there has been increasing interest in social prescribing as a means of addressing complex health, psychological and social issues presented in primary care [3], as well as its potential to reduce health inequalities.[4] Social prescribing is widely promoted as a way of making primary care (GP practice) more sustainable and receives significant support at the policy level [5]; for example, NHS England appointed a national clinical champion for social prescribing in 2016 [6]. Yet, “current evidence fails to provide sufficient detail to judge either success or value for money” (p1) [5]. This study addresses this gap through evaluation of the impact of a social prescribing intervention on people with type 2 diabetes living in an ethnically diverse urban area of high socio-economic deprivation.

Diabetes is a major public health issue; the number of people in the UK with diabetes is expected to rise to over six million by 2035 and 85-90% of these people will have type 2 diabetes. If no changes are made to the way type 2 diabetes is assessed and treated, the costs to the NHS are estimated to increase to £17 billion by 2035, with associated increases in the wider costs to society estimated at over £22 billion.[7, 8] Economic analyses show that most of these NHS costs are for treating the complications of diabetes and, as many people with type 2 diabetes have poorly controlled blood glucose, there is scope for improvement in their disease management, resulting in fewer complications and cost savings.[9] However, people with type 2 diabetes often have one or more other long term condition [10] and type 2 diabetes is often associated with mental health conditions, such as anxiety and depression, which can negatively affect an individual’s ability to manage their type 2 diabetes and other long term conditions. [11] Multi-morbidity, the presence of two or more long term conditions, is an increasing individual and societal problem associated with poor quality of life and increased mortality and accounts for over 70% of total healthcare spend.[12].

The service being evaluated, Ways to Wellness (http://waystowellness.org.uk/), delivers social prescribing to people aged 40-74 with at least one of eight long term conditions (diabetes type 1, diabetes type 2, Chronic Obstructive Pulmonary Disease, Asthma, Heart Failure, Coronary Heart

Disease, Epilepsy, Osteoporosis). Please see box 1 below for a detailed description of the intervention. There are 33 GP practices in Newcastle upon Tyne, UK of these 17 are able to refer their patients to Ways to Wellness. Thus, of the total number of GP practices in Newcastle upon Tyne about half are able to refer their patients to Ways to Wellness.

The current study focusses on evaluation of Ways to Wellness social prescribing intervention for people with type 2 diabetes. People with type 2 diabetes form a large part of the entire population that are defined by Ways to Wellness referral criteria. The invitation to participate in the research will include all 33 GP practice in Newcastle upon Tyne. Evaluation data are available for the entire population defined by Ways to Wellness referral criteria in all GP practices that agree to participate in this research.

Data sharing agreements, between NHS Digital and Newcastle Gateshead Clinical Commissioning Group (CCG), and between Ways to Wellness and Newcastle Gateshead CCG; (with the North of England Commissioning Support Unit (NECS) as data processor) are already in place. As planned our proposed data extraction will make use of existing data-sharing agreements, information governance and data extraction procedures (please see page 14 for further details). This data extraction strategy will also support data analyses of long term conditions other than type 2 diabetes, which are of interest to the evaluation of social prescribing, but which are not directly linked to the aims and outcomes of the currently proposed analyses.

7. STUDY AIMS AND OBJECTIVES

Aims

This multimethod study aims to evaluate the impact and costs of a community based Link Worker social prescribing intervention on the health and health care utilisation of adults aged 40-74 with type 2 diabetes (T2D), living in a multi-ethnic area of high socio-economic deprivation.

The three linked work packages (WPs) outlined below comprise study objectives.

Objectives

1. **WP1**: To measure the short-term (one year) and long-term (two and three year) effects of the social prescribing intervention targeting adults with T2D on HbA1c (primary outcome), and changes in secondary outcomes of body mass index (BMI), systolic blood pressure (SBP) and cholesterol values, smoking and health-care utilisation. We will also provide a range of estimated intervention effects based on comparing the treated group with a number of relevant control groups.

2. **WP2**: To measure the cost-effectiveness of the social prescribing intervention for healthcare utilisation and each of the outcomes HbA1c, BMI, SBP, cholesterol and EQ-5D-5L. From the

perspective of a health service provider, costs and benefits will be compared for those individuals in the intervention compared with individuals who were eligible for treatment but did not take part in the intervention. The robustness of the results will be investigated using sensitivity analysis.

3. **WP3**: To use ethnography (participant observation and interviews) to examine patients' engagement with the intervention and whether and how social prescribing leads to changes in patients' lives. We also ask how the impact of the intervention permeates beyond the individual patient, and affects family and wider social networks. This includes an exploration of the lived experiences of the link workers delivering social prescribing locally.

As an adjunct to the ethnography, we will use remote interviews during and immediately after the lockdown to explore the impact of the COVID-19 pandemic on service users and link workers.

8. STUDY POPULATION

Inclusion and exclusion criteria for intervention and control groups

Community-dwelling adults aged 40 to 74 years, with type 2 diabetes with or without comorbidity or disease-related complications or a diagnosis of depression or anxiety. People with advanced (end stage) disease as determined by their GP will be excluded.

9. SETTING AND TARGET POPULATION

The setting for this study is Newcastle upon Tyne, UK: an inner-city area of high social deprivation (Population N=111,557), ranked 40th most deprived in England according to the Index of Multiple Deprivation.[13]

The intervention group are drawn from 17 GP practices (and five associated satellite clinics) that are able to refer their patients to the Ways to Wellness intervention: hereafter referred to as the Ways to Wellness GP practices. The Ways to Wellness GP practices are detailed in Table 1, which shows ward level population statistics by age, gender ethnicity and index of multiple deprivation (IMD) score, for wards that include the 17 Ways to Wellness GP practices and their five satellite clinics.

The control groups are drawn from these Ways to Wellness GP practices and from other GP practices in Newcastle upon Tyne.

10. ETHICAL APPROVALS AND PROTOCOL DEVELOPMENT

Ethical approval from three separate bodies are required as follows:

- WPs 1 & 2 NHS Integrated Research Application System (IRAS) (approved, Project ID: 238970)

- WP 1 (EQ 5D only) Faculty of Medical Sciences Newcastle University Research Ethics Committee (approved)
- WP 3 Durham University Department of Anthropology Ethics Committee (approved)
- COVID-19 qualitative study. Durham University Department of Anthropology Ethics Committee (approved)
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The protocol is structured according to the ethical requirements of each WP.

11. WORK PACKAGES 1 & 2

The protocol for WPs 1 & 2 been developed using Standard Operating Procedure developed by Newcastle Biomedicine Clinical Research Platforms, with reference to SPIRIT and CHEERS checklists downloaded from the EQUATOR network on 29th November 2017 http://www.equator-network.org/ .

WPs 1 and 2 comprise analyses of routinely collected and pseudonymised health data, (primary care and Secondary User Service data), collated from all the GP practices in Newcastle upon Tyne that agree to participate in the study: here after the study participating GP practices. WPs 1 and 2 will also include analyses of pseudonymised Ways to Wellness service data as supplied to North of England Commissioning Support Unit (NECS) through usual Ways to Wellness service procedures.

Patients who have chosen to opt out of participation in research will be flagged in GP registers, identified by their NHS numbers and excluded from any data extraction processes. This includes patients in GP practices that have agreed to participate in the research and are study GP practice.

Box 1: Ways to Wellness intervention

Ways to Wellness http://waystowellness.org.uk/ is a community based link worker social prescribing intervention for people with long term conditions. Intervention development was based on extensive pilot work and co-produced with people with long term conditions, over eight years (2007 to 2015). [14-16] From March 2018 Ways to Wellness will be delivered by two not-for-profit organisations, Mental Health Concern and First Contact Clinical. Originally two other not for profit organisations (HealthWORKS (2015 to 2016) and Changing Lives (2015 to 2017) were also involved in the delivery). [17] Ways to Wellness is funded (£12 million) via a Social Impact Bond by the (then) Newcastle West Clinical Commissioning Group, the Big Lottery, the Cabinet

Office and Bridges Ventures. The service began in April 2015 and is on target to recruit approximately 1500 participants annually over seven years (total N=10,500). Approximately 41% of these people have type 2 diabetes.

Ways to Wellness aims to improve health related outcomes and quality of life of people with long term conditions by increasing their confidence and ability to manage their illness, and to reduce costs and/or improve value to the NHS in their treatment. The Ways to Wellness intervention has four key objectives:

1. to improve participant health related behaviours, [18] such as increased physical activity, [19] healthier eating, weight loss, smoking cessation, [20] moderation of alcohol intake [21] and good sleep routines;
2. to improve participant self-care including use of aids and accessing support to facilitate getting dressed, cleaning and shopping;
3. to encourage better self-management of participants' long term conditions including screening attendance;
4. to promote social integration, including accessing work, volunteering and other social opportunities [22].

Box 1 (continued)

The 'Wellbeing Star' [23] self-assessment tool is included as part of the Ways to Wellness intervention. The 'Wellbeing Star' is a tool which helps service users to assess their state across eight parameters (lifestyle; self-care; symptom management; work, volunteering and activity; money; home environment; personal relationships; and positive feeling). Whilst using this tool service users are encouraged to identify areas they wish to improve and decide how they will monitor their progress.

Ways to Wellness is designed to provide an efficient referral mechanism for primary care practitioners [24] optimising referral practices through the facilitation of patients' access to community based support and social engagement, thus supplementing the care patients receive from the NHS. [25, 26] Ways to Wellness provider organisations are allocated to geographical clusters of GP practices and are tasked with building relationships with these GP practices.

Patients are referred by their GP to Ways to Wellness and assigned to a Link Worker, who is a trained facilitator. Link Workers use behaviour change techniques including motivational interviewing, goal-setting and feedback to promote the aims of Ways to Wellness.

Link Workers provide the following for each of their assigned clients: (a) individual assessment, motivational interviewing and action planning [27] (b) completion of the 'Well-being' star self-assessment tool at baseline and six monthly up to 24 months, (c) support and guidance to access community services (e.g. walking groups, physical activity classes and welfare rights advice) (d) promotion of volunteering opportunities and (e) promotion of improved self-care. The Ways to Wellness intervention is highly personalised involving face-to-face contacts in community settings, and where necessary, domiciliary visits. Contact is also made, where appropriate, via email, text and telephone. All contacts vary in duration and frequency in accordance with individual client need but overall engagement with Ways to Wellness can be up to two years.

Through promotion of healthier behaviours and taking account of the wider determinants of health, Ways to Wellness aims to improve health related outcomes (e.g. weight loss and improved blood biomarker values) [28], reduce long term condition related complications (e.g. diabetic retinopathy) and the likelihood of developing co-morbidity, and improve quality of life. The strong focus on addressing the wider determinants of health through Link Worker facilitated access to services like, welfare rights, debt and housing advice and employment support emphasises the potential for the intervention to address health inequalities.

Ways to Wellness is a community based service and, since April 2015, has been managed via Ways to Wellness Ltd., which is a special purpose vehicle set up to oversee the delivery of the service. [22]. Link Workers in the provider organisations have comparable job descriptions and roles, and all receive the same training resulting in a National Vocational Qualification Health Trainer award. All Link Workers meet quarterly to share good practice. Common training, roles and ongoing reflection of practice of Link Workers across the provider organisations is an attempt to mitigate threats to the fidelity of intervention delivery.

Box 1 (continued)

Table 1. Population statistics at ward level: age, gender ethnicity and index of multiple deprivation (IMD) score, for wards with Ways to Wellness GP practices and patients

Ward	Total population	Population age (years % of total)			Gender (% of total)		Ethnicity (Non-white % of total)	IMD score (Ward - highest most deprived)	IMD quintile (5 most deprived)
		0-14	25-64	≥ 65	Male	Female			
Elswick	13198	38.5	51.5	10	53.2	46.8	46.9	50.7	5
Parklands	9971	28.7	54.1	17.2	48.8	51.2	12.5	8.1	1
Fawdon	10090	32.0	51.3	16.7	48.7	51.3	7.9	36.6	5
Denton	10500	30.3	48.1	21.7	47.5	52.6	2.5	31.7	5
Fenham	10954	36.2	49.2	14.6	47.7	52.3	15.2	28.8	4
Wingrove	13685	47.0	45.4	7.6	54.2	45.8	50.2	28.9	4
Blakelaw	11507	33.8	50.5	15.6	47.7	52.3	16.0	35.8	5
Benwell & Scotswood	12694	33.3	51.7	14.7	48.5	51.5	9.1	43.3	5
Newburn	9536	37.8	52.8	19.3	48.5	51.5	2.1	28.5	4
East Gosforth	10145	30.7	53.8	15.5	49.6	50.4	10.6	10.3	2
Westerhope	9196	22.7	50.9	26.4	47.9	52.1	2.3	14.8	3
Other wards with substantial Ways to Wellness recruitment									
Lemington	10228	30.4	53.8	15.7	48.2	51.8	2.4	30.4	4
Westgate	10059	46.2	47.7	6.4	56.0	44.0	34.9	41.1	5
Kenton	11605	34.5	52.8	16.4	49.4	50.6	13.2	38.9	5
Mean % by category		34.4	51.0	15.6	49.7	50.3	16.1	30.6	

Index of Multiple Deprivation: IMD Quintiles: 1 ≤ 8.49 (Least deprived); 2= 8.5 - 13.79; 3 =13.8 - 21.35; 4 = 21.36 - 34.17; 5 ≥ 34.18 (Most deprived)

12. WP 1 & 2 PRIMARY AND SECONDARY OUTCOME DATA AND STUDY DESIGN

Data collation and storage

Data to be analysed will comprise pseudonymised individual level data that will be collected, collated and pseudonymised by the North of England Commissioning Support Unit (NECS).

The collation of data from a large number of records and the application of unique study numbers will ensure robust pseudonymisation of all the data that are made available to the research team, whilst facilitating analyses of individual level data.

Study participation is by agreement with GP practices, however any patients, registered in a study participating GP practice, who have opted out of research will be identified by their NHS numbers and excluded from all data extraction and associated research.

There are three sources of individual level patient data.

(1) Routinely collected primary care data with associated meta-data

(2) Secondary Service User data (Health care utilisation)

(3) Intervention group Ways to Wellness service data (data routinely collected by Ways to Wellness and returned to NECS)

These outcome data for analyses will comprise data collected between 1st April 2012 and 31st March 2020 for patients who were registered with any study participating GP practice in Newcastle upon Tyne, UK and who were born between 31st March 1940 and 1st April 1984. Study participating GP practices comprise both those GP practices that are able to refer their patients to the Ways to Wellness service (Ways to Wellness GP practices) and a number of GP practices that were not part of the Ways to Wellness initiative and are not able to refer their patients to the Ways to Wellness service, but that have agreed to participate in the study and supply patient data (study participating GP practices). Data from patients registered with both Ways to Wellness GP practices and other GP practices in Newcastle upon Tyne are required for the proposed analyses.

1. Routinely collected primary care data with associated meta-data

Primary care data with associated meta-data that is included in GP records, as detailed in table 2 below, will be accessed by NECS from primary care records in study participating GP practices (defined above). These data will be accessed as individual level data records that are identified by QOF related READ codes. These data will then be collated into anonymised data records by NECS. NECS will apply unique study numbers to organise and identify the individual level data records in these collated data.

Subject to research and information governance approvals NECS will retain a ‘coding list’ that links the unique study numbers applied to these study data by NECS to patient NHS numbers. This coding list will not be made available to the research team, but will secure the opportunity for follow-up studies, subject to all necessary agreements at a future date, if this is considered appropriate at the time. The research team are not requesting access to NHS numbers.

Anonymised data that are made available to the research team for analyses, as detailed in table 2, will include, where possible, all available dates for each data item to determine the time points when these data were routinely collected in primary care (or where appropriate, the time points when bio-marker data analyses, such as analyses of HbA1c values, were completed).

Primary care data extraction and collation will be done by NECS as follows:

Eligible participants' (aged 36 to 70 on 01.04.2011) QOF primary care data, as detailed in table 2 with values taken for each quarterly data point, for data collected between April 1st 2011 and 31st March 2019. These data were received 27th June 2019.

Eligible participants' (aged 36 to 70 on 01.04.2011) SUS primary care data, as detailed in table 2 with values taken for each quarterly data point, for data collected between April 1st 2013 and 31st March 2019. These data were received 27th June 2019.

Study participant list

The patients identified by NECS through these primary care data extractions will form a 'study participant list'.

2. Secondary Users Service data

We will request Secondary User Service (SUS) data, via NECS, that applies to study eligible participants (both Ways to Wellness service users and control groups) using the following strategy. The 'study participant list' collated by NECS in the extraction and collation of primary care data described above will be used to inform a request to NHS digital for SUS data specific to the patients on the study participant list. These patients will be identified for this purpose by their NHS numbers. These SUS data will be collated by NECS and pseudonymised using the unique study numbers for individual patients. This will allow linkage between primary care and SUS data.

3. Ways to Wellness service data

We will request Ways to Wellness service data (data routinely collected by ways to Wellness and returned to NECS) for patients on the study participant list, via NECS, as above. These patients will be identified by their NHS numbers, which are recorded by the Ways to Wellness service. This strategy will ensure that any patient who has opted out of participation in research will be identified by their NHS number and will therefore not be included in the study participant list and their Ways to Wellness service data will not be accessed or made available to the research team.

The Ways to Wellness service data will be linked to the other study data by NECS, using study participant NHS numbers. NECS will then apply the unique study numbers as above to ensure these data are pseudonymised, before they are made available to the research team. The research team will not have access to patient NHS numbers.

Table 2: Ways to Wellness primary care data request

Exclude	
End stage disease	As determined by patients' GP
Opted out data use for research	As shown on GP records

Metadata, demographic details (etc.)

Study number (unique ID)	To organise individual level records
Birth year (and month)	To determine age
Sex	
Ethnicity	See table 3
LSOA number	To determine socio-economic status eg. as IMD score (NECS will use postcode data to provide LSOA numbers as part of the pseudonomisation.
GP practice code	To derive Ways to Wellness provider organisation

Long term condition	READ code preferred	Read codes also acceptable (to be confirmed)	Diagnosis (Y/N + date)
Diabetes	C10E% and C10F%	C10 C109J C109K C10C C10D C10F% (excluding C10F8 Reaven's Syndrome) C10G% C10H% C10M% C10N% PKyP	
Diabetes resolved	21263	212H	
Diabetes in remission	C10P	C10P0 C10P1	
Refractory angina			
COPD	H3	H31% (excluding H3101, H31y0 and H3122) H32% H36-H3z (excluding H3y0 and H3y1) H5832	
Depression	E112%	E0013 E0021 E113% E118 E11y2 E11z2 E130 E135 E2003 E291 E2B E2B1 Eu204 Eu251 Eu32% (<u>excludes</u> Eu32A Eu32B Eu329) Eu33% Eu341 Eu412 [2]	
Asthma	H33%	173A H3120 + all codes starting H33 (except H333) - see note [1]	
Hypertension	G2	G20% G24-G2z (excluding G2400 G2410 G24z1 and G27) Gyu2 Gyu20	
Heart failure	G58%	G1yz1 662f-662i [1]	
Epilepsy	F25% with exclusions	(Excluded from F25: F2501 F2504 F2511 F2516 F256% F258 to F25A F25G (and from July 2013:) F25H F25y4) F1321 SC200	
Osteopososis	N330%	(All N330 codes except N3308, N3309) N3312 N3313 N3316 N3318-B N331H-M NyuB0 NyuB1 NyuB8 N3314 N3315 N3746 NyuB2 see note [1]	
Event			Date of event(s)
Acute MI	G30% (excluding G30A)	G35% G38% Gyu34 Gyu36	
Stroke (all types)	G61% and G64%	G61% (excluding G617) G63y0-G63y1 G66% (excluding G669) G6760 G6W G6X G65-G654 G656-G65zz Gyu62-Gyu66 Gyu6F Gyu6G ZV12D	

Outcome measurement (for each occasion with date of collection/analysis)

	Read Code preferred	Alternative read codes (to be confirmed)	value	date
HbA1c	42W5	(% values), DM007, DM008, DM009		
BMI	22K5 , 22K7, 22K (+ numeric BMI >30)	22KC 22KD 22KE 22KB (+ numeric BMI >30		
Height				
Weight				
Total Cholesterol	44P + value <5	44OE 44PH 44PJ 44PK (all need a value of <5)		
HDL cholesterol				
LDL Cholesterol				
O/E - blood pressure reading	246%	(all 246 codes except 2460 246H 246I 246K 246L 246M and 246h-k)		
Smoking status	Current smoker	1372-1376		
	Ex-smoker	1377-137B		
	Never smoked tobacco	1371		

Table 3: Ethnicity

A	British or Mixed British
B	Irish
C	Any other white background
	Mixed
D	White and Black Caribbean
E	White and Black African
F	White and Asian
G	Any other mixed background
	Asian or Asian British
H	Indian
J	Pakistani
K	Bangladeshi
L	Any other Asian background
	Black or Black British
M	Caribbean
N	African
P	Any other black background
	Other Ethnic Groups
R	Chinese
S	Any other ethnic group
Z	Not Stated
99	Not Known

Intervention and health service cost data

Cost data for the intervention programme will be provided by the Ways to Wellness management group and other cost data, such as for health care utilisation, will be extracted from available standard information sources.

Data sharing and storage

Data sharing will be actioned by adding Newcastle University as an additional (sequential) data processor to data sharing agreements that are already in place between NHS Digital and Newcastle Gateshead CCG, and between Ways to Wellness and Newcastle Gateshead CCG; (with NECS as data processor). Newcastle University will only be able to access these data in pseudonymised form. All appropriate data storage and IGT agreements and procedures will be detailed and complied with.

Study design

Study design exploits natural experimental methods and analyses of routinely collected health data to evaluate the effectiveness and cost effectiveness of the Ways to Wellness intervention. The Intervention and Control groups for analyses are summarised in table 4 below, with estimate of bias for each of these comparisons.

Table 4 Summary of intervention and control groups and estimate of bias for Ways to Wellness intervention effectiveness analyses

Intervention Group	Control Group	Estimate	Bias
Study-eligible patients in Ways to Wellness GP practices [a] who were in receipt of the intervention at time t^b	Study-eligible patients in Ways to Wellness GP practices who were not in receipt of the intervention at time t and who go on to receive the intervention at time $t+1^b$	τ_1	If the intervention is randomly assigned across patients this should provide a consistent estimate of the short run effect of the intervention. If individuals in the greatest need are first to receive the intervention then any significant finding may be an overestimate. As $t \rightarrow t+1$ this comparison estimates an intensity of intervention effect – individuals who have been on the programme for over a year compared to individuals who have just started the programme.
Study-eligible patients in Ways to Wellness GP practices who were in receipt of the intervention during the study period	Study-eligible patients in WTW GP practices not receiving intervention during the study period	τ_2	If the intervention is randomly assigned this should provide a consistent estimate of the intervention effect. If individuals in the greatest need are first to receive the intervention then any significant finding may be an overestimate. If individuals who may benefit from intervention refuse the intervention, and this is related to our outcomes of interest, then the bias may be in either direction.
Study-eligible patients in WTW GP practices receiving intervention over the study period	Study-eligible patients not in WTW GP practices	τ_{3a}	If, pre-intervention, the intervention group and the control group have similar trends in their outcomes, and if there are no changes that may affect the control group differentially to the intervention group, this approach should provide the best estimate of the average effect of intervention on the treated. This would give the complier average causal effect. If there are non-SP interventions for the control group that are beneficial then we would underestimate the benefits of SP intervention.
Study-eligible patients in WTW GP practices	Study-eligible patients not in WTW GP practices	τ_{3b}	If pre-intervention, the intervention group and the control group have similar trends in their outcomes, and if there are no changes that may affect the control group differentially to the intervention group, this approach should provide the best estimate of an intention-to-treat effect. This will be different, and we expect lower, than the average effect of intervention on the treated (τ_{3a}) since our intervention group contains untreated individuals. However it has the benefit of overcoming any problems regarding intervention assignment in SP practices.
[a] patients registered with GP practices listed in table 1 [b] time at which an individual engages with the intervention [c] 1st April 2015 to 31st March 2018 /20			

13. RECRUITMENT WP 1 & 2

The study relies on analyses of anonymised routine primary care, secondary user service data (health care utilisation data) and Ways to Wellness service data that will be accessed via NECS for a study participant list described above. Recruitment is thus at the level of GP practices in Newcastle upon Tyne that agree to participate in the study and is subject to the provision for those patients who have opted out of participation in research to be identified by their NHS numbers by NECS and excluded from the data provided to the research team.

14. WP 1 EQ 5D DATA COLLECTION

The protocol for WP1 EQ 5D data collection has been developed using Standard Operating Procedure TM-010-00 developed by Newcastle Biomedicine Clinical Research Platforms http://www.ncl.ac.uk/crp/assets/documents/SOP%20TM-01000%20Protocol%20dev%20(final).pdf) and ACT Consortium Guidance, Qualitative Methods Protocol Template, *Chandler, C.I.R., and Reynolds, J. (2013)* Available at www.actconsortium.org/qualitativemethodsguidance

This element of WP1 aims to explore service users' perspectives quality of life over one year of service delivery and comprises WtW service users' questionnaire data at baseline and 12 months follow-up.

Design

WtW service users will be invited to complete a quality of life (EQ-5D-5L) questionnaire at baseline and 12 month follow-up. These questionnaires will be distributed by WtW Link Workers or other suitable staff appointed by the WtW delivery organisations for the purpose of distributing these questionnaires. The research team will supply an information and consent form, together with a questionnaire for each service user. The consent forms include participant contact details. The Link Workers or other staff appointed for this purpose will take informed consent from each participant before distributing each baseline questionnaire. They will add a WtW study ID number to each questionnaire (at baseline and 12months) and consent form before giving these to the relevant service user. Envelopes will be supplied for collection of questionnaires. Consent forms will be collected separately from the questionnaires.

The completed questionnaires will be returned to the WtW evaluation team either by post or by collection from the WtW delivery organisations. The evaluation team will be able to link the questionnaire data taken at different time-points by means of the WtW study ID numbers. In certain cases WtW service users may require help to read the questionnaires. In these circumstances the WtW delivery staff will be responsible for facilitating this in an appropriate manner to ensure that the Link Worker relationship with their clients is not adversely affected.

The consent forms will include contact details for people who agree to participate in the EQ5D questionnaire study. Contact details are included so that the evaluation team can contact those people who leave the WtW service before the 12 month follow-up point. Follow-up will be undertaken by the research team. Participants will be sent a questionnaire by post together with an information leaflet, reply paid envelope. After 10 days, those who have not responded will be called by telephone and asked to complete their questionnaire. Non-responders will be given the option to complete their follow up questionnaire over the telephone. We will attempt to contact non-respondents by telephone on two occasions.

Inclusion criteria

WtW service users in one year of intervention delivery (expected 1st July 2018 to 30th June 2019) who have consented to participate in this questionnaire study.

Target number of participants

All WtW service users recruited over the duration of the questionnaire study (expected 1st July 2018 to 30th June 2019).

15. WP3 ETHNOGRAPHY

WP3 will use ethnographic methods to examine, in depth, how the intervention produces change. This work will be conducted in two main parts, an ethnography of service users (Eth1) and an ethnography of Link Workers (Eth2), supplemented by a case study. In Eth 1, we will examine how the social worlds of patients shape their responses to the intervention, and the impact of the intervention within their social worlds, for example how lifestyle changes are negotiated as family practices. Eth 2 will provide an in-depth picture of how the intervention unfolds within the provider organisations, with a particular focus on the Link Workers' roles as they are performed on a daily basis. Finally, we will develop a case study examining referral into walking interventions. This case study is designed to probe how Ways to Wellness connects with a type of intervention that is often highlighted as a desirable destination for patients in social prescribing interventions.

Design of WP3

Eth 1: Service user ethnography

A sample of key participants will be followed from the beginning to the end of fieldwork, to allow us to follow their 'social prescribing journey', whether they remain engaged with the service, 'complete' or drop out. We will observe their engagement with services, and explore practices within their families and social networks.

Specifically, within the first six months of fieldwork the researcher will visit key participants (i.e. service users) in their home, or meet them at a venue of their choice, to conduct a semi-structured interview exploring their experiences of the intervention. Each participant will be interviewed again in the final six months of fieldwork, to follow up their experiences of the intervention. Between the two interviews, opportunities for participant observation will be pursued as far is feasible and will include spending time in participants' homes, accompanying participants to appointments with their Link Worker and accompanying participants to 'prescribed' activities (e.g. walking groups, volunteering activities etc.) depending on the preferences of the participant. Further episodes of participant-observation will be pursued opportunistically, and will include friends and family of key participants. With up to 12 participants, particularly those who are less willing to invite the researcher into their lives for participant observation, we will use photo-elicitation interviews to supplement the standard interviews and provide a more complete and complex picture of the intervention.

It is likely that a few key participants will not speak English fluently. Language barriers will be overcome by working alongside paid translators to conduct semi-structured and photo-elicitation interviews (see below). We will not pursue participant observation where language barriers would pose problems, as the presence of a translator would be unhelpful for this form of data collection.

As necessary, we plan to be flexible and responsive and to deploy methods that appear most productive as we progress, in light of practical issues such as the willingness of a diverse range of participants to engage with particular approaches, and the success of different methods in helping us gather rich data.

Eth 2: Link Worker ethnography

Following interviews with service users, focus groups will be undertaken with Link Workers to gain their perspective on the intervention. We will also use participant observation to explore how the roles of Link Workers are shaped within the two provider organisations over a period of three months at each organisation, and we will 'shadow' a subsample of Link Workers in their routine daily practice to explore how they deliver the intervention.

Prescribing into walking interventions: case study

This case study draw on our ethnographic data collected with Link Workers and service users with reference to walking interventions, supplemented by further data collected on walking interventions within the locality covered by Ways to Wellness. Interviews will be conducted with all major walking intervention providers to establish the walking intervention 'landscape' over the period that Ways to Wellness has been running, and participant observation will be conducted with two to three walking interventions, including a walking group.

Participant recruitment

Eth 1: Service user ethnography

Between 18 and 22 key participants will be recruited, 9-11 from each voluntary sector provider. Key participants will be purposively sampled on the basis of age, gender, ethnicity, employment status, social class, service provider, length of time engaged with the intervention, reason for remaining with/leaving the intervention. Based on these specifications, we will ask a manager at each provider organisation to select the sample for us to approach. This is to avoid Link Workers selecting 'good' patients. However, Link Workers will be asked to use their personal knowledge of clients to advise if any of those selected should not be approached because participating in the study would be likely to cause them distress (for example, because of a mental health problem). We do not plan to exclude participants with mental illness, but will exclude those considered by their Link Worker likely to be distressed by participation in the study.

We plan to recruit friends and family opportunistically during participant observation with key participants. As well as engaging with family and friends during participant observation, we will undertake semi-structured interviews with up to 12 family members and friends to explore their perspectives on the intervention. Family members or friends will be approached only with the permission of the relevant key participant.

Eth 2: Link Worker ethnography

We will conduct focus groups with up to 26 Link Workers. Participant observation will be undertaken within the main offices of the each of the two provider organisations, mainly within the shared offices of Link Workers. Up to 16 Link Workers will be shadowed over 5-15 days each in their routine practice.

Prescribing into walking interventions: case study

Those providing walking interventions in the area covered by Ways to Wellness will be identified and interviews will be requested. Participant observation will be conducted with members of walking interventions.

Fieldwork and data collection

Eth 1: Service user ethnography

Initial (flexible) interview guides will ask about participants' experiences of WtW, and whether and how they have made changes to their everyday practices as a result of their interactions with Link Workers. During follow-up interviews we will pursue questions and phenomena identified during participant observation and discuss observations made during participant observation that may be misconstrued if they are not directly discussed. Semi-structured interviews offer an opportunity to access meanings and motivations beyond what can be ascertained during participant observation. Semi-structured interviews with family and friends will explore their perspectives on the intervention. This will allow us to examine further how key participants negotiate their responses to the interventions within their social worlds, as well as to investigate the impact of the intervention on those close to key participants.

Participant observation

We will use participant observation, or 'hanging out', to help build a thick description of the everyday experience of the WtW programme. This will involve spending time with participants in their homes, as they engage with the intervention, and in other parts of their everyday lives, as feasible and acceptable to them.

Photo-elicitation interviews

Asking participants to take photographs during their everyday lives and using the photographs to elicit information during a subsequent interview provides insights that standard interviews sometimes fail to capture. This method provides a powerful means of accessing participants' reflections on mundane and everyday experiences, and will provide unique insights into how the intervention plays out in their everyday lives, enabling us to capture information from those hesitant to share their lives via participant observation. We will loan digital cameras to participants, or participants can choose to use their own mobile phones, and ask them to photograph aspects of their lives they consider relevant to their diabetes.

Eth 2: Link Worker ethnography

Focus Groups

Focus groups will be undertaken with Link Workers to gain their perspective on the intervention. We will organise up to three focus groups at each provider organisation. All Link Workers will be invited to participate, and we anticipate that group sizes will be up to 8. Focus groups will be facilitated by our post-doctoral research associate, and a second post-doctoral research associate will assist, managing the recording and taking notes. Questions will focus on 'what works' for clients, and how 'what works' varies for different clients.

Participant Observation

The researcher will spend part of her working week over a period of three months at each organisation, initially gaining a broader understanding of the structure and ethos of the provider organisations and understanding the professional practice/s of Link Workers. Following this, the researcher will spend more focused time shadowing a smaller number of LWs (up to 16) as they go about their daily working routines. At opportune times during the working day, short informal interviews will be conducted with Link Workers, during which they will be asked to reflect on their practice.

Data Analysis

Qualitative data will comprise semi-structured interview and focus group transcripts as well as ethnographic field notes. Thematic content analysis will be conducted iteratively alongside fieldwork, and will be achieved via coding all textual data and synthesising codes and categories into emerging themes of understanding. We will compare the interview narratives ('what is said') with the observations ('what is done'). The participant-produced images will also be analysed in their own right, as they can help the ethnographer to understand how participants represent themselves, their environments and experiences. Line-by-line coding will be conducted using Nvivo to identify themes in the data, and memos will be used to assist in the process of moving from content-based descriptive themes that are relevant to our research questions to more conceptual themes that incorporate differences, similarities, inconsistencies and contradiction in the data. Analysis will involve synthesising and theorising the data, and re-contextualising this new knowledge by considering it in the context of other research.

Compensation for participants and provider organisations

Key service user participants will receive a token of thanks (a £20 shopping voucher) at their first and last interviews, and if they participate in a photo-elicitation interview a further £20 shopping voucher. Provider organisations will receive payments for the time Link Workers spend in the focus groups, at the pro rata salary rate, by way of compensating for lost staff time.

16. <u>MULTIMETHODS</u>

The final stage of the research involves bringing the multiple datasets together to narratively integrate the findings, [29] capitalising on the multiple methods thereby enhancing overall interpretation of the study.

17. IMPACT OF COVID 19 ON SERVICE USERS (ADDITIONAL QUALITATIVE RESEARCH STUDY)

DESIGN

A qualitative study using telephone semi-structured interviews with participants in the before-and after EQ-5D-5L study during and immediately after the first full UK lockdown period.

SAMPLING AND RECRUITMENT

Participants in the EQ-5D-5L study who were contacted to complete their 12 month follow-up questionnaire during the lockdown period and who agree to participate in a telephone interview about their experiences during the pandemic.

DATA COLLECTION

EQ-5D-5L questionnaire and semi-structured interview covering: experiences of ill-health; impacts of COVID-19 on interviewees, their conditions and their household members; support needed or received including social prescribing; and, feelings about life after lockdown. Interviews will be conducted over the telephone and recorded with permission. Demographic data will be collected on age, gender, ethnicity, employment, education, housing tenure/type/composition and household income.

DATA ANALYSIS

Interview data transcribed and transcripts will be read and re-read and a coding frame developed. Line-by-line coding will be used to identify descriptive and conceptual themes, using NVIVO to assist with data management. Analysis of EQ-5D-5L data will use descriptive statistical techniques to characterise health related quality of life among the sample, at baseline and after the March 'lockdown'. A regression discontinuity design will be used to estimate the impact of the lockdown on health related quality of life.

18. RESEARCH GOVERNANCE

Newcastle University will act as the sponsor for this research.

Management of the study will be overseen by a study management committee, chaired by Professor Sally Wyke, Glasgow University. Overall responsibility and day-to-day management of the project will be undertaken by the Principal Investigator, and will include all investigators.

19. PLANS FOR DATA MANAGEMENT, CURATION AND STORAGE.

All data will be pseudonymised before these are made available to the study team. All data will be kept in secure password protected files fully compliant with the data Protection Act, the requirements of Newcastle University procedures and the Information Governance Toolkit.

20. PUBLICATIONS

The proposed study builds on earlier qualitative work that was conducted between June 2015 and June 2016, funded by a grant from the UK Government’s Cabinet Office (Grant No. A1543). The first paper resulting from this qualitative evaluation has been published: Moffatt S, Steer M, Penn L, Lawson S: What is the impact of 'social prescribing'? Perspectives of adults with long-term health conditions. *BMJ Open* 2018, 0:e015203. doi:10.1136/bmjopen-2016-015203. [30]

The protocol paper was published in January 2019 and is available via open access, Moffatt S, Wildman J, Pollard TM, Penn L, O'Brien N, Pearce MS, Wildman JM. Evaluating the impact of a community-based social prescribing intervention on people with type 2 diabetes in North East England: mixed-methods study protocol, BMJ Open Jan 2019, 9 (1) e026826; DOI: 10.1136/bmjopen-2018-026826

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