ISRCTN13880272 https://doi.org/10.1186/ISRCTN13880272

Impact of a community based social prescribing intervention on people with type 2 diabetes 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

Submission date 22/05/2018	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 25/05/2018	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 31/05/2023	**Condition category** Nutritional, Metabolic, Endocrine	[_] Individual participant data

Plain English summary of protocol

Background and study aims

The number of people in the UK with type 2 diabetes (T2D) is expected to rise to six million by 2035. Poor diabetes control uses a great deal of NHS resources and can have severe impacts. It is important that people with T2D are given proper help. If no changes are made to the way T2D is treated, the costs to the NHS are estimated to be about £17 billion by 2035. It is very difficult for busy health professionals to provide the full range of support that is necessary. Health programmes that involve individuals and communities more directly in the management of their own health conditions and support them to adopt healthier behaviours can improve health and reduce NHS costs. Social prescribing is a form of support for people with long-term conditions like T2D. The aim of this study is to assess the effectiveness of a new programme that has been developed over eight years by local health and voluntary sector organisations with input from patients and the public. It involves referral to a trained 'Link Worker' who supports and empowers people with T2D to make healthier lifestyle choices, to improve their health, self-care and quality of life. People can access the programme through their GP surgery. On referral, the Link Worker will discuss healthier lifestyle options with each person individually and help them to plan positive health behaviour changes. Link Workers will also provide information about other community services, such as, walking groups, welfare rights or employment advice and support people to attend. The aim of this study is to assess the effect of the programme, how much it costs, and how it affects other family members and the wider community.

Who can participate?
Patients aged 40 to 74 with one or more long-term health conditions, including type 2 diabetes, living in an urban area of high socio-economic deprivation

What does the study involve?
Information is collected from GP records on 1,600 people who received the intervention and it is compared in three ways: (i) with people at GP practices which don't have the intervention; (ii) with people from the same practice who are eligible but don't take up the intervention, and (iii) people who entered the programme at the beginning with people who entered it later. The costs and effectiveness of the programme are compared to existing treatment to see whether the intervention is value for money compared to other treatments. Observations and interviews with people using the service are used to find out how they experience it, in order to find out what works, why it works and what does not work and why. During the study, a group of service users and Link Workers advises researchers on involving people with the study, participant information, what the findings mean and producing user-friendly information about the study. The results of the study will help decide whether this type of programme should be funded in the future.

What are the possible benefits and risks of participating?
The benefits and risks of taking part in the intervention are entirely separate from any benefits or risks from taking part in the evaluation. The effectiveness evaluation relies on analyses of routinely collected primary care data. As these data are supplied to the research team in anonymised form and stored in accordance with NHS compliant information governance procedures no risks are expected. The benefits of the evaluation will be the effect on future service provision rather than any specific benefit to current participants. Those people who have opted out of use of their health service data for the purpose of research will be identified through usual primary care procedures and their data will not be used as part of this evaluation.

Where is the study run from?
Newcastle University (UK)

When is the study starting and how long is it expected to run for?
April 2012 to April 2021

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Suzanne Moffatt

Contact information

Type(s)
Public

Contact name
Dr Suzanne Moffatt

Contact details
James Spence Institute
Royal Victoria Infirmary

Newcastle University
Newcastle upon Tyne
United Kingdom
NE1 4LP

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

Ways to Wellness effectiveness evaluation V1

Study information

Scientific Title

Effectiveness of Ways to Wellness, a community-based social prescribing intervention, on people aged 40 to 74 with type 2 diabetes, living in an ethnically diverse socio-economically deprived urban area, using natural experimental methods to assess change differences in measures of health status and health behaviours, including health-care utilisation, between intervention recipients and three control groups, with cost-effectiveness and ethnography studies to assess impact

Acronym

SPRING_NE

Study objectives

Ways to Wellness social prescribing intervention will impact the health status and health behaviours, including health care utilisation of people with type 2 diabetes living in areas of socio-economic deprivation

Ethics approval required

Old ethics approval format

Ethics approval(s)

IRAS (London Committee), 04/04/2018, IRAS project ID 238970

Study design

Natural experiment with three comparison groups and associated ethnographic study

Primary study design

Observational

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Type 2 diabetes

Interventions

Participants with one or more long term health conditions, including type 2 diabetes, are offered the Ways to Wellness service and referred by their GPs in WtW participating practices. These practices number 17 of the 33 GP practices in the locality (city). There are no randomisation procedures. The allocation of GP practices to participate or not in the WtW service depends on the historical organisation of primary care services in the locality (city) where the study takes place.

Those who participate in the WtW service (intervention group) are allocated to a trained link worker, who is trained in behaviour change techniques and supports them to improve their health behaviours and to access other services relevant to their individual health and social needs. Ways to wellness link workers are employed by two not-for-profit community based organisations to deliver the intervention. Link workers are tasked to develop sustained, supportive relationships with people referred from primary care and they support their clients to identify goals and encourage goal achievement by linking them into community, voluntary and NHS sector services.There is no prescribed time scale for participant engagement in the service, but a period not exceeding 24 months is expected.

There are three comparison groups:
1. Comparison by time of engagement in the WtW service
2. Comparison with those in participating GP practices who are eligible for the WtW service, but who do not participate in the service over the duration of the study
3. Comparison with those who fulfil the individual eligibility criteria but are registered with non-participating) GP practices in the city

A team of university researchers will use a number of different research methods, known as ‘mixed methods’. In study one, information on 1,600 people from GP records will be compared in three ways: (i) with people in practices who don’t have the intervention; (ii) with people from the same practice who are eligible but don’t take up the intervention, and (iii) people who entered the programme at the beginning with people who entered it later. In study two, the costs and effectiveness of the programme will be compared to existing treatment to see whether the intervention is value for money compared to other treatments. In study three, observations and interviews with people using the service will be used to find out how they experience it. This will help us find out what works, why it works and what does not work and why. During the study, a group of service users and Link Workers will advise researchers on involving people with the study, participant information, what the findings mean and producing user-friendly information about the study.

Intervention Type
Behavioural

Primary outcome(s)
The effectiveness study (work package 1) will assess change in measures of health status in the intervention group and three comparator groups. The primary outcome measure is short-term (one year) and long-term (two and three year) effects of Ways to Wellness intervention targeting adults with type 2 diabetes on changes in HbA1c. These data will be assessed using routinely collected primary care data. These data are collected as part of each participants usual health care and the timepoints when data are collected will vary with individual need. However, for the purpose of data extraction data will be used at quarterly intervals. The first data will be from three years before the first patient is recruited to the WtW service (three years prior to 01 /04/2015) and up to 31/03/2020.

Key secondary outcome(s))
Weight, body mass index (BMI), systolic blood pressure (SBP) and total cholesterol values, smoking status and health-care utilisation, assessed using routinely collected primary care and secondary service user data. These data are collected as part of each participants usual health care and the timepoints when data are collected will vary with individual need. However, for the purpose of data extraction data will be used at quarterly intervals. The first data will be from three years before the first patient is recruited to the WtW service (three years prior to 01/04/2015) and up to 31/03/2020.

Completion date
30/04/2021

Eligibility

Key inclusion criteria
1. Aged 40 to 74 years
2. One or more long term health conditions, including type 2 diabetes
3. Living in an urban area of high socio-economic deprivation
4. Community dwelling adults

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Upper age limit
74 years

Sex
All

Total final enrolment
8400

Key exclusion criteria
1. People with end stage disease
2. The effectiveness analysis relies on routinely collected primary care data. people who have opted out of the use of their primary care data for research purposes will be identified by GP practices and their data will not be included in the study

Date of first enrolment
01/04/2015

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Newcastle University
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle University

ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are not expected to be made available by the research team as their use of these data relies on agreements with other parties and compliance with information governance procedures that do not provide them with permission to share these data.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2023	31/05/2023	Yes	No
Protocol article	protocol	01/01/2019	28/07/2020	Yes	No