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Community pharmacies mood intervention study (CHEMIST)

Submission date	Recruitment status	[X] Prospectively registered
06/03/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/03/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/04/2023	Mental and Behavioural Disorders	

Plain English summary of protocol

Current plain English summary as of 04/04/2019:
Background and study aims
About 30% of the UK population has long term physical health problems. Many of those people also suffer from depression, which can end up making their physical health problems worse, lowering their quality of life and doubling healthcare costs. Mild/Sub-Threshold depression often goes undetected and untreated despite the fact it also can worsen a person's health and functioning and is a major risk factor for depression. A previous study found that a treatment called collaborative care reduced depression symptoms and nearly halved the number of people who developed major depression in older adults with sub-threshold depression. The program included a type of therapy called behavioural activation, which is a short form of cognitive behavioural therapy (a type of talking therapy that helps people change the way they think and behave), and could be run by people with no professional qualifications who are trained /supported by experts. Community pharmacies may provide an excellent setting for this type of program for people with health problems and sub-threshold depression. The aim of this study is to look at whether the treatment can be adapted and if it can be delivered by suitably trained community pharmacy staff to adults with mild depression and long term health problems.

Who can participate?
Adults with sub-threshold depression and who have one or more long-term health conditions.

What does the study involve?
In the initial phase of the study, all participants receive the treatment, called 'Pharmacy Support'. In the second phase of the study a computer randomly allocates (like flipping a coin) participants to receive the Pharmacy Support (50 people) or the usual NHS care (50 people) they normally receive. No treatment is stopped and all participants continue to receive all the care and support they usually do whilst taking part in the study. Participants receiving the Pharmacy Support are contacted by a Healthy Living Advisor from their local pharmacy who arranges their first pharmacy support session. The pharmacy support sessions involve working with a Healthy Living Advisor to plan changes that aim to improve mood and overall wellbeing. The sessions usually take place over the telephone, or if people prefer they can take place face-to-face in their local pharmacy. Participants speak with their Healthy Living Advisor up to 6 times over a four month period and each session lasts for about 15-20 minutes. During the sessions,

participants are provided with information to help them think about their difficulties and what they may be able to do to improve some of them, and the Healthy Living Advisor supports them to work through the self-help workbook. All participants in the study are then sent a questionnaire after four months to complete and return to the study team. Participants may also be asked if they would like to take part in an interview to discuss their views about mental wellbeing and the pharmacy support they received as part of the study. Pharmacy staff will also be invited to take part in an interview to discuss their views about delivering the Pharmacy Support and providing this support within the context of the community pharmacy.

What are the possible benefits and risks of participating?
It is not known whether taking part in this study will help participants, but participants may receive additional support which is not usually available to people from their local pharmacies. Taking part could help improve the treatment offered to people suffering from low mood or depression in the future. There are no anticipated risks to people taking part in the study, but it will take up some of their time to complete the questionnaires and some time will be spent working through the pharmacy support sessions and the associated activities.

Where is the study run from?
The study is run from the University of York and takes place in at least six pharmacies in England (UK)

When is the study starting and how long is it expected to run for?
January 2017 to April 2019. The study was later extended to November 2019.

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

Who is the main contact?
1. Dr Liz Littlewood (public)
liz.littlewood@york.ac.uk
2. Dr David Ekers (scientific)
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Previous plain English summary:
Background and study aims
About 30% of the UK population has long term physical health problems. Many of those people also suffer from depression, which can end up making their physical health problems worse, lowering their quality of life and doubling healthcare costs. Mild/Sub-Threshold depression often goes undetected and untreated despite the fact it also can worsen a person’s health and functioning and is a major risk factor for depression. A previous study found that a treatment called collaborative care reduced depression symptoms and nearly halved the number of people who developed major depression in older adults with sub-threshold depression. The program included a type of therapy called behavioural activation, which is a short form of cognitive behavioural therapy (a type of talking therapy that helps people change the way they think and behave), and could be run by people with no professional qualifications who are trained /supported by experts. Community pharmacies may provide an excellent setting for this type of program for people with health problems and sub-threshold depression. The aim of this study is to look at whether the treatment can be adapted and if it can be delivered by suitably trained community pharmacy staff to adults with mild depression and long term health problems.

Who can participate?
Depressed adults who have one or more long-term health conditions.

What does the study involve?
In the initial phase of the study, all participants receive the treatment, called 'Pharmacy Support'. In the second phase of the study a computer randomly allocates (like flipping a coin) participants to receive the Pharmacy Support (50 people) or the usual NHS care (50 people) they normally receive. No treatment is stopped and all participants continue to receive all the care and support they usually do whilst taking part in the study. Participants receiving the Pharmacy Support are contacted by a Healthy Living Advisor from their local pharmacy who arranges their first pharmacy support session. The pharmacy support sessions involve working with a Healthy Living Advisor to plan changes that aim to improve mood and overall wellbeing. The sessions usually take place over the telephone, or if people prefer they can take place face-to-face in their local pharmacy. Participants speak with their Healthy Living Advisor up to 6 times over a four month period and each session lasts for about 15-20 minutes. During the sessions, participants are provided with information to help them think about their difficulties and what they may be able to do to improve some of them, and the Healthy Living Advisor supports them to work through the self-help workbook. All participants in the study are then sent a questionnaire after four months to complete and return to the study team. Participants may also be asked if they would like to take part in an interview to discuss their views about mental wellbeing and the pharmacy support they received as part of the study.

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When is the study starting and how long is it expected to run for?
June 2016 to April 2019

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

Who is the main contact?
1. Dr Liz Littlewood (public)
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Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
32240

Study information

Scientific Title
Community pHarmaciEs Mood Intervention STudy (CHEMIST): Feasibility and Pilot Study

Acronym
CHEMIST

Study objectives
Feasibility Study:
The aim of the feasibility study is to adapt a bespoke Enhanced Support Intervention for implementation by community pharmacy staff to people with sub-threshold depression and long-term conditions, and to test the proposed study processes (recruitment, assessment, intervention and collection of outcome measures) to be used in the pilot RCT.

Pilot RCT:
The aim of the pilot RCT is to examine delivery of the bespoke Enhanced Support Intervention against usual care in a community pharmacy setting, and to quantify and evaluate the flow of participants (screening, eligibility, recruitment, intervention uptake and retention, and follow-up rate) to determine the feasibility of conducting a larger definitive RCT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East – Newcastle and North Tyneside 2 Research Ethics Committee, 18/11/2016, ref: 16/NE/0327

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Depression

Interventions
Feasibility study:
All participants receive the Enhanced Pharmacy Support Intervention (ESI). The ESI will be adapted for use with individuals with sub-threshold depression and long-term conditions, and will consist of four elements: Behavioural Activation focused self-help support; Proactive follow-up; Symptom monitoring; and Decision supported signposting. It will be delivered by suitably

trained pharmacy support staff experienced in delivery of extended pharmacy roles (such as smoking cessation behavioural change approaches) over 4-6 sessions in a 4 month period either over the phone or face-to-face in the privacy of pharmacy consulting rooms. Participants are followed up at 4 months post-recrutiment.

Pilot RCT:
Participants are randomised in a 1:1 ratio using the independent online randomisation service provided by the York Trials Unit) to one of two group.

Intervention group: Participants receive the Enhanced Pharmacy Support Intervention (ESI) over 4-6 sessions in a 4 month period either over the phone or face-to-face in the privacy of pharmacy consulting rooms, as in the feasigbility study.

Control group: Participants receive usual primary care management of sub-threshold depression offered by the GP or other local community provision.

Participants in both groups are followed up at 4 months post-randomisation.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Feasibility Study:
1. Recruitment and attrition rates
2. Quality of data collection at baseline and 4 months
3. ESI adherence
4. Process evaluation is undertaken through qualitative interviews with participants, ESI facilitators and pharmacy staff

Pilot RCT:
Self-reported depression severity is measured by the Patient Health Questionnaire (PHQ9) at baseline and 4 months.

Secondary outcome measures
Pilot RCT:
1. Prevention of depression measured by binary depression scores on the PHQ9 at baseline and 4 months
2. Anxiety is measured using the GAD7 at baseline and 4 months
3. Health Related Quality of Life measured by the SF-12v2 at baseline and 4 months
4. Health State Utility measured by the EQ-5D at baseline and 4 months
5. Health Service Use, collected by a bespoke questionnaire (adapted AD-SUS) at baseline and 4 months
6. Participant's use of Enhanced Support Intervention, collected from intervention facilitator records at 4 months
7. Process evaluation is undertaken using qualitative interviews with participants, pharmacy staff and GPs at 4 months

Overall study start date

01/01/2017

Completion date
30/11/2019

Eligibility

Key inclusion criteria
1. Adults (male or female, aged 18 years and over)
2. One or more long-term conditions (Arthritis, Cancer, Cardiovascular Conditions, Diabetes, Respiratory Conditions, Stroke).
3. Sub-threshold depression (screen positive with 2-4 symptoms confirmed by diagnostic assessment tool)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Feasibility study: 20-30. Pilot RCT: 100

Total final enrolment
68

Key exclusion criteria
Current participant exclusion criteria as of 04/04/2019:
1. Alcohol or drug dependence
2. Cognitive impairment
3. Bipolar disorder or psychosis/psychotic symptoms
4. Actively suicidal (ascertained by eligibility screening interviews)
5. Currently in receipt of psychological therapy

Previous participant exclusion criteria:
1. Alcohol or drug dependence
2. Cognitive impairment
3. Bipolar disorder or psychosis/psychotic symptoms
4. Acutely suicidal (ascertained by eligibility screening interviews)
5. Currently in receipt of psychological therapy

Date of first enrolment
22/03/2017

Date of final enrolment
05/04/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Whitworth – Your Family Pharmacy
17 Beresford Buildings,
Thorntree
Middlesbrough
United Kingdom
TS3 9NB

Study participating centre
Whitworth – Your Family Pharmacy
13-15 Woods Terrace,
Murton
Seaham
United Kingdom
SR7 9AD

Study participating centre
Whitworth – Your Family Pharmacy
7 Healaugh Park
Yarm
United Kingdom
TS15 9XN

Study participating centre
Norchem, Queens Park Medical Centre
Farrer Street
Stockton-on-Tees
United Kingdom
TS18 2AW

Study participating centre

Norchem, Crossfell Pharmacy
The Berwick Hills Centre
Ormesby Road
Middlesbrough
United Kingdom
TS3 7RP

Study participating centre
Marton Pharmacy
4 Marton Estates Square
Stokesley Road
Marton
Middlesbrough
United Kingdom
TS7 8DU

Study participating centre
University of York
Department of Health Sciences/York Trials Unit
Heslington
York
United Kingdom
YO10 5DD

Sponsor information

Organisation
Tees, Esk and Wear Valleys NHS Foundation Trust

Sponsor details
Research and Development
Flatts Lane Centre
Flatts Lane
Normanby
Middlesbrough
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United Kingdom
TS6 0SZ
+44 1642 283501
s.daniel@nhs.net

Sponsor type
University/education

Website
https://www.dur.ac.uk/

ROR
https://ror.org/04s03zf45

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

Publication and dissemination plan
Dissemination plans include publication of the protocol and pilot RCT outcomes in high-impact peer-reviewed journals. Study summaries will be produced for a range of audiences including service users, health provides and commissioners. The findings will be presented at conferences and disseminated via presentations at a local level (local pharmacy networks and local authorities).

Intention to publish date
30/06/2020

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/05/2019	05/06/2019	Yes	No
Results article		03/02/2022	15/02/2022	Yes	No
Results article		01/03/2022	26/04/2023	Yes	No
HRA research summary			28/06/2023	No	No