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Caring for caregivers (C4C)

Submission date	Recruitment status	[ ] Prospectively registered
04/01/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/01/2017	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/02/2024	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Psychosis is a serious mental disorder in which thought and emotions are impaired, causing a person to lose touch with reality. The main symptoms of psychosis are experiencing hallucinations (hearing and/or seeing things that aren't there) and delusions (holding strong beliefs that aren't shared by others, such as believing people are trying to harm them). People experiencing psychosis need help with their mental and physical health and daily activities (e.g. shopping, finances). Care is mostly provided by family/friends, often in their 70s or 80s. Caregiving limits caregivers' own leisure activities and availability to work/volunteer, causing additional stress, poor health and financial problems. The Department of Health recognise that supporting caregivers ultimately also helps the people they care for, but current recommendations are hard to access and time-consuming. Positive Written Disclosure (PWD) is a type of therapy which involves writing about positive life experiences. Studies have shown that it can reduce health/complaints and feelings of anxiety depression in many different groups of people. The aim of this study is to find out whether PWD is helpful in older adult caregivers of people experiencing psychosis, and if the therapy is acceptable.

Who can participate?
Caregivers over 50 years old who are caring for someone with psychosis

What does the study involve?
Participants are randomly allocated to one of three groups. Those in the first group take part in PWD. This involves spending 20 minutes a day for three days engaging in positive writing exercises. Instructions are provided to help guide people through the activity, in which participants are asked to think of a positive memory, and write about their deepest thoughts and emotions in relation to this memory. Those in the second group take part in a writing task that does not involve PWD for 20 minutes a day for three days. This involves looking at a series of images and writing down what can be seen in the pictures factually. Those in the third group are asked to continue as normal and do not take part in a writing activity. At the start of the study and then again after one, three and six months, participants in all groups complete a number of questionnaires to assess their mood and mental wellbeing.

What are the possible benefits and risks of participating?
Participants may benefit from trying a new treatment, and all participants will have the opportunity to provide their feedback on the study and interventions. This feedback will inform

the next steps of the research programme. There is a small risk of participants not finding any benefit from the intervention; and participating in the study will involve participants giving up some of their own time i.e. to complete the questionnaires.

Where is the study run from?
Sussex Partnership NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2017 to October 2018

Who is funding the study?
The Dunhill Medical Trust (UK)

Who is the main contact?
Miss Cassie Hazell
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
32688

Study information

Scientific Title
Caring For Carers (C4C): Pilot randomised controlled trial of Positive Written Disclosure for Older Adult Carers of people with psychosis

Acronym
C4C

Study objectives
The aim of this pilot randomised controlled feasibility trial is to investigate the feasibility of conducting a definitive trial looking at the efficacy of Positive Written Disclosure (PWD) for older adult carers of people with psychosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Lancaster Research Ethics Committee, 24/11/2016, ref: 16/NW/0757

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

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Mental Health, Primary sub-specialty: Study not assigned to a MH Clinical Studies Group; UKCRC code/ Disease: Other/ General symptoms and signs

Interventions
At the start of the study, the statistician responsible for randomisation will generate a group allocation sequence that will link participant IDs to either positive written disclosure (PWD), writing control activity (WC) or no writing task (NWC). Block randomisation will be used, and will be carried out by a statistician independent of the research team. The statistician will not have access to any of the personal information of the participants and will randomise using the participant identification numbers. Members of the research team will be blind to the size of the blocks. Randomisation will be carried out using a 1:1:1 ratio. The group allocation will be concealed from participants until after the baseline assessment is completed. The researcher responsible for carrying out the assessments will be blinded to the group allocation.

Positive Written Disclosure (PWD): Participants take part in Positive Written Disclosure (PWD), which is a self-directed and time-limited therapy. PWD will require participants to take 20 minutes out of their day, for three consecutive days to write continuously about a positive memory or experience. Participants will be encouraged to describe this positive event in a lot of detail, focussing on the subjective experience. Participants will be provided with a workbook and a set of writing instructions within which to complete the PWD writing tasks. The PWD workbook and instructions are based on the materials used in similar research studies that were found to be acceptable to participants. It is hoped that taking some time to focus on this positive experience or memory will help to improve the wellbeing of our participants (older adult caregivers of people experiencing psychosis).

Writing Control (WC) task: Participants are asked to complete a non-emotive writing task. The participants allocated to this group will also receive a workbook and a set of writing instructions.

The writing task will require participants to look at images of different rooms within a house and describe them as accurately and in as much detail as possible. The images were selected to be neutral (not provoke any strong positive or negative feelings) and also rich in detail – so that participants have enough to write about. The final images were selected by our lived experience advisory panel. Participants will be asked to write about these images continuously for 20 minutes over three consecutive days. The instructions for the writing task encourage participants to not give their feelings or opinions towards the images, and instead stick to the facts.

Non-Writing Control (NWC) task: Participants will not be asked to complete any writing tasks over the course of the study, and will receive no intervention. Participants in this group will be encouraged to carry on with their usual activities, as if they were not part of the research study. So as to maintain researcher blinding, this group will receive a writing pack that is empty.

Quantitative data will be collected at baseline (before randomisation), and 1, 3 and 6 months post randomisation. Participants in the writing conditions (PWD or WC) will be invited to complete an exit interview discussing their experiences of the study and the writing tasks.

Intervention Type
Behavioural

Primary outcome(s)
Mood is measured using the Positive and Negative Affect Scale (PANAS) at baseline, 1, 3 and 6 months.

Key secondary outcome(s))
1. Symptoms of anxiety and depression are measured using the Depression Anxiety and Stress Scale (DASS 21) at baseline, 1, 3 and 6 months
2. Self-efficacy is measured using the General Self-Efficacy Scale (GSES) at baseline, 1, 3 and 6 months
3. Wellbeing is measured using the Caregiver Wellbeing and Support Scale (CWSv2) at baseline, 1, 3 and 6 months
4. Alexithymia is measured using the Toronto Alexithymia Scale (TAS 20) at baseline only
5. General health and health economics is measured using the EQ-5D at baseline, 1, 3 and 6 months
6. Satisfaction with leisure activities is measured using the Leisure Time Satisfaction Measure (LTS) at baseline, 1, 3 and 6 months

Feasibility outcomes:
1. Recruitment rate is measured as the proportion of participant who provide consent, compared to those who are referred, at baseline.
2. Retention rate is measured as the percentage of participants that provide data at all time points (baseline, and 1, 3 and 6 months) at the end of the study
3. Adherence to the intervention is measured as the percentage of participants that complete writing on all three days, the percentage of participants that write for 20 minutes each day, and the percentage of participants that complete their writing on the three consecutive days, at the end of the study

Completion date
01/10/2018

Eligibility

Key inclusion criteria
1. Classified as a primary caregiver as defined by the Royal College of General Practitioners (2011, p. 9): “any person who provides unpaid support to a partner, child, relative or friend who couldn’t manage to live independently or whose health or wellbeing would deteriorate without this help.”
2. Aged 50 years or over
3. Providing care for someone with a psychosis diagnosis - psychosis is defined here as including the following diagnoses:
3.1. Schizophrenia
3.2. Schizoaffective disorder
3.3. Schizotypal Personality Disorder
3.4. Delusional disorder
3.5. Psychosis not otherwise specified
3.6. Bipolar
3.7. Depression with psychotic features
4. Able to read, write and communicate in English

Participant type(s)
Carer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
50 years

Sex
All

Key exclusion criteria
Currently receiving or have confirmed plans to engage in psychological therapy of any form (including family therapies).

Date of first enrolment
09/01/2017

Date of final enrolment
01/03/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sussex Partnership NHS Foundation Trust
Headquarters
Swandean
Arundel Road
Worthing
United Kingdom
BN13 3EP

Sponsor information

Organisation
University of Sussex

ROR
https://ror.org/00ayhx656

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Dunhill Medical Trust

Alternative Name(s)
The Dunhill Medical Trust, Dunhill Medical Trust, DunhillMedical, DMT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

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?
Results article	protocol	08/11/2022	14/11/2022	Yes	No
Protocol article		21/11/2017		Yes	No
HRA research summary	recruitment analysis		28/06/2023	No	No
Other publications		17/12/2019	19/12/2019	Yes	No
Participant information sheet	Participant information sheet	21/11/2017	13/02/2024	No	Yes
Participant information sheet		11/11/2025	11/11/2025	No	Yes