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Stigma of living as an autism carer: a brief psycho-social support intervention (SOLACE)

Submission date
04/10/2017

Recruitment status
No longer recruiting

Registration date
13/10/2017

Overall study status
Completed

Last Edited
23/04/2020

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Stigma is widespread in families with autism and has a strong impact on the psychological well-being of caregivers of autistic children. Autism caregivers are found to have significantly lower psychological well-being than carers of any other disabilities. Research has shown that stigma lowers self-esteem, produces feelings of self-blame, reduces feelings of hope and increases feelings of loneliness. For caregivers, it additionally increases the feelings of caregiver burden. To protect caregivers from the harmful effects of stigma will have a positive effect on their mental health and subsequently on their caregiving abilities. The aim of this study is to address this unmet need of carers of autistic children by developing and testing a group-based stigma protection intervention. As there are currently no such interventions available it is unknown what will be effective, acceptable and achievable with such an intervention. It is therefore necessary to carry out a small study to assess the feasibility and acceptability of the intervention for a future larger study.

Who can participate?
Any family caregiver aged over 18 who lives in the county of Bedfordshire and provides care for young children (aged up to 10 years) who are about to receive an autism diagnosis, are currently obtaining a diagnosis, or have received a diagnosis within the past 12 months.

What does the study involve?
Caregivers who agree to take part are randomly allocated to either the control group or to the experimental group. Caregivers allocated to the control group receive no intervention whereas caregivers allocated to the experimental group take part in an 8-week group-based stigma protection program led by a facilitator. The aim of the intervention program is to increase the psychological well-being of caregivers by equipping them with skills to cope with stigma and to prevent internalisation of stigma. To do this, variables that are found to affect the stigma-mental health relationship are targeted such as self-esteem, self-blame, compassion and acceptance, positive meaning of caregiving and social support. There are eight weekly 90 minute sessions; three of these sessions are face to face and the remaining sessions are delivered online via video conference as this is considered to be most practical and beneficial for caregivers. The psychological well-being of the participants is assessed at the end of the intervention (week 8) and 6 weeks follow up

What are the possible benefits and risks of participating?
The possible benefits of the group sessions are that participants may feel better equipped to cope with the negative experiences of stigma and feel an improvement in their well-being and caregiving abilities. It is unlikely that there are negative effects of taking part in the study.

Where is the study run from?
The study is situated in Bedfordshire and the face to face meetings are likely to be held in Bedford or Luton (UK)

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

Who is funding the study?
The University of Bedfordshire and Autistica (UK)

Who is the main contact?
Dr Chris Papadopoulos
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2.0

Study information

Scientific Title
The development and evaluation of a stigma protection intervention for family caregivers of autistic children: a feasibility study

Acronym
SOLACE

Study objectives
The research question of this study is: To what extent is a brief psycho-social stigma protection intervention for family caregivers of young children on the autism spectrum designed primarily to improve psychological well-being, feasible and acceptable?

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Bedfordshire Research Ethics Committee - submission pending

Study design
Parallel-group randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Community

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
The impact of stigma on the psychological health of carers of autistic children

Interventions
There are two arms of this parallel RCT; the experimental group and the control group which will run at the same time. Participants will be randomly allocated to either group via assigning the random numbers from random number tables to the experimental group. Participants in the control group will receive no treatment. Participants allocated to the intervention group will take part in an 8-week group-based intervention program run weekly for 90 minutes each. The intervention will be delivered face to face as well as via video conference. The sessions will target the modifiable psychosocial variables found to moderate the relationship between stigma and mental health such as self-esteem, self-blame, compassion, positive meaning in caregiving, acceptance and social isolation. A combination of psycho-education, cognitive re-structuring and acceptance commitment therapy techniques will be used in the sessions.

Intervention Type
Behavioural

Primary outcome measure
1. The primary outcome measure proposed to measure the preliminary effectiveness of the intervention is the psychological well-being of the participants, measured with the Mental Health Inventory (MHI-5) at baseline, mid-intervention (week 4), at the end of the intervention (week 8) and 6 weeks follow up
2. The retention rate is measured by how many caregivers consented versus how many caregivers completed the intervention and all of the assessments at the end of intervention
3. The willingness to be randomised is measured as part of the baseline data collection by asking participants if they are happy to be randomly allocated to either group, before the intervention commences
4. The consent rate is assessed by comparing how many caregivers were sent the information pack (including consent forms) versus how many consented to take part
5. Reasons for not participating in the study; People who did not consent are asked to provide a reason why they do not wish to consent to take part
6. The feasibility and acceptability of the intervention and outcome measurement tools, assessed using a qualitative focus group after the end of the intervention phase. The participants are also invited to provide their opinions on whether and how the intervention could be refined to increase the likelihood of effectiveness of a future pilot intervention study.
7. The acceptability of the intervention and outcome measures is measured quantitatively using

a brief questionnaire at the end of the intervention
8. Initial estimate for sample size calculation for a future main RCT, estimated using pre- and post- means and standard deviations of the primary outcome measure (psychological well-being, MHI-5)

Secondary outcome measures
Secondary measures to measure the preliminary effectiveness of the intervention:
1. Stigma and self stigma, measured using Perceived Public Stigma Scale (PPSS); Perceived Courtesy Stigma Scale (PCSS), Affiliate Stigma Scale
2. Self-esteem, measured using Rosenberg's 10-item Self-Esteem Scale
3. Self-compassion, measured using Self-Compassion Scale-Short Form (SCS–SF)
4. Positive meaning in caregiving, measured using the 11-item scale devised by Werner and Shulman and in 2013
Self-Blame Scale adapted from Werner and Shulman (2013)
5. Social isolation, measured using Short-form UCLA Loneliness Scale (ULS-4)

Measured at baseline, mid-intervention (week 4), week 8 and 6 weeks post-intervention. Both control and experimental group complete the same measures.

Overall study start date
17/10/2016

Completion date
01/04/2019

Eligibility

Key inclusion criteria
1. Aged over 18
2. Reside within the county of Bedfordshire
3. Provide care for young children (aged up to 10 years) who are about to receive an autism diagnosis, are currently obtaining a diagnosis, or have received a diagnosis within the past 12 months
4. Have access to the internet to be able to take part in the group sessions
5. Speak and understand English

Participant type(s)
Carer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
32

Total final enrolment
17

Key exclusion criteria
1. The child they care for has been diagnosed more than 12 months ago
2. The child they care for is above 10 years of age
3. Participants reside outside Bedfordshire
4. Have no access to the internet
5. Do not speak and understand English

Date of first enrolment
01/03/2018

Date of final enrolment
30/09/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Autism Bedfordshire
Autism Bedfordshire
Salamander House
2 – 10 St John's Street
Bedford
United Kingdom
MK42 0DH

Study participating centre
Luton Borough Council (Special Educational Needs Service Team)
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Sponsor information

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Sponsor type
University/education

ROR
https://ror.org/0400avk24

Funder(s)

Funder type
Charity

Funder Name
Autistica

Alternative Name(s)

Funding Body Type
Government organisation

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

Location
United Kingdom

Funder Name
University of Bedfordshire

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location

United Kingdom

Results and Publications

Publication and dissemination plan
It is planned to submit the study's protocol later this year. The trial results will be disseminated through planned publication in a high-impact peer review journal submitted approximately a year after the trial end date. This study is part of a PhD thesis which will also be published via Ethos.

To support the development of the planned intervention an online survey was carried out to explore the views of the autism community on what makes an intervention successful. Results of this survey will be submitted for publication later this year to a high-impact peer review journal.

Intention to publish date
01/04/2020

Individual participant data (IPD) sharing plan
The 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	26/02/2019	13/03/2019	Yes	No
Results article	results	01/12/2020	23/04/2020	Yes	No