ISRCTN15144652 https://doi.org/10.1186/ISRCTN15144652

Healthy Parent Carers: a research study to test ways to improve the health and wellbeing of parent carers of disabled children and whether the trial design is acceptable to participants

Submission date
22/10/2018

Recruitment status
No longer recruiting

Registration date
25/10/2018

Overall study status
Completed

Last Edited
27/08/2021

Condition category
Other

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

Plain English summary of protocol

Current plain English summary as of 22/05/2019:
Background and study aims
Parent carers of disabled children tend to have poorer mental and physical health than other parents. Researchers and parent carers have co-developed a programme to improve the health and wellbeing of parent carers of disabled children. The programme is led by parent carers and involves working with others in a group to encourage behaviours associated with better health and wellbeing. The behaviours are called CLANGERS: Connect, Learn, be Active, Notice, Give, Eat well, Relax and Sleep. Parent carers are given the Healthy Parent Carer Guide with information related to each session. The programme has been delivered once over six weekly sessions. Two parent carer facilitators led a group with seven participants. They felt the programme was valuable in building resilience and identifying specific strategies to deal with the challenges that parent carers commonly face. The aim of this study is to see whether the programme can be delivered in the community through organisations that have links with parent carers, and to test whether it improves health and wellbeing and is good value for money.

Who can participate?
Parent carers of children with special educational needs and disabilities aged up to 25 years

What does the study involve?
Parent carers are randomly allocated to either receive the group intervention or to receive the Healthy Parent Carer Guide information as online materials only. The group intervention is 12 modules which can be delivered over six 4-hour or 12 2-hour sessions. The online materials reflect the content of the group sessions. All parent carers complete questionnaires before and after the programme and 6 months later. The aim is to find out whether parent carers are willing to take part in a study like this, whether enough people sign up and stay to the end of the study, and whether the ways of measuring health and wellbeing are appropriate. If this study shows the group programme can be delivered and evaluated in this way, a larger study will be planned to test whether the programme improves parent carers' health and wellbeing.

What are the possible benefits and risks of participating?
Participants receive access to the Healthy Parent Carers programme, either through access to online resources or by taking part in a group programme. All participants receive shopping vouchers as a thank you for their time completing the questionnaires. Participants are asked to complete questionnaires and some are asked to take part in interviews. If any of the questions make them feel uncomfortable, participants may decline to answer any particular questions. Taking part in the programme involves thinking about experiences and challenges as a parent carer. If during the course of this project the investigators become concerned about a participant's wellbeing, this will be discussed with the participant. If the investigators have any safeguarding concerns they will be duty bound to contact a medical professional or the study safeguarding officer.

Where is the study run from?
University of Exeter Medical School (UK)

When is the study starting and how long is it expected to run for?
July 2018 to June 2020

Who is funding the study?
National Institute for Health Research (NIHR) (UK)
National Lottery Community Fund

Who is the main contact?
1. Dr Gretchen Bjornstad
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2. Dr Christopher Morris
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Previous plain English summary:
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Study website
http://sites.exeter.ac.uk/healthyparentcarers/

Contact information

Type(s)
Public

Contact name
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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT03705221

Secondary identifying numbers
40120; PB-PG-0317-20044

Study information

Scientific Title
Healthy Parent Carers programme: feasibility study of a peer-led group-based health promotion intervention for parent carers of disabled children using a parallel group randomised controlled trial design

Study objectives
The aim of this feasibility study is to test whether the Healthy Parent Carers group-based programme can be delivered in community settings by trained peer-facilitators and online materials; and whether a randomised controlled trial to evaluate the effectiveness and cost-effectiveness of the intervention is both feasible and acceptable to participants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Exeter Medical School Research Ethics Committee, 20/08/2018, ref: 18/06/174

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
http://sites.exeter.ac.uk/healthyparentcarers/files/2018/03/Participant-Information-Sheet-Version-2.pdf

Health condition(s) or problem(s) studied
Public health; parent carers of children with special educational needs or disability

Interventions
Current interventions as of 22/05/2019:
Method of randomisation: 8-24 participants will be randomised at each of 6 sites when recruitment is completed at each site. A computer-generated randomisation sequence will be used to assign the participants in each site to the intervention and control arms. A block randomisation scheme will be implemented to ensure equal allocations in the number of participants allocated to each trial arm, stratified by group delivery site. The allocation sequence will be concealed from investigators using an online central randomisation service set up and maintained by the Exeter Clinical Trials Unit.

The Healthy Parent Carers programme is a health promotion intervention to improve health and wellbeing for parent carers of disabled children. In this feasibility study, parent carers will be randomised to either a peer-led group-based programme with access to online materials (intervention) or to receiving online materials only (control). The group-based programme content is 12 modules, which can be delivered over six 4-hour or 12 2-hour sessions.

The programme aims to improve health and wellbeing by:
1. Encouraging parent carers to take time to reflect on their health and wellbeing
2. Inspiring motivation and self-efficacy
3. Introducing a set of simple, health-promoting actions with practical examples
4. Prompting participants to use evidence-based behaviour change techniques
5. Encouraging peer support and identification of positive social support outside of the group
6. Providing opportunities for creating a shared social identity and sharing of experiences

The intervention content is detailed in the Facilitator's Manual and consists of:
1. Information including free online videos and reflective activities to encourage behaviours associated with better health and wellbeing (i.e. CLANGERS)
2. Strategies to support self-regulatory behaviour change techniques (BCTs) – i.e. goal setting, self monitoring, barrier identification and problem solving
3. Encouragement of peer support, identifying sources of support outside of groups, and developing a shared social identity to increase motivation and confidence

The Healthy Parent Carers Guide online materials reflect the content of the group sessions, and provide space to write down reflections, prompts to set specific goals and a self-monitoring diary.

Follow-up: post-intervention and 6 months post-intervention.

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Follow-up: 15 weeks after randomisation and 40 weeks after randomisation (approximately 6 months after the end of the intervention).

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 22/05/2019:
Mental wellbeing is measured using the Warwick-Edinburgh Mental Well-being Scale (WEMWBS) at baseline, post-intervention and 6 months post-intervention.

Previous primary outcome measures:
Mental wellbeing is measured using the Warwick-Edinburgh Mental Well-being Scale (WEMWBS) at baseline, 15 weeks post-randomisation and 40 weeks post-randomisation

Secondary outcome measures
Current secondary outcome measures as of 22/05/2019:
1. Depression symptoms are measured using the Patient Health Questionnaire-9 (PHQ-9) at baseline, post-intervention and 6 months post-intervention.
2. Health-related quality of life is measured using the EuroQol 5 Dimensions (EQ-5D-5L) at baseline, post-intervention and 6 months post-intervention.
3. Parental protective factors such as parental resilience, social connections, concrete support in times of need, and support of children's social and emotional competence are measured using the Parents' Assessment of Protective Factors (PAPF) at baseline, post-intervention and 6 months post-intervention.
4. Participation in health-promoting activities is measured using the Health Promoting Activities Scale (HPAS) at baseline, post-intervention and 6 months post-intervention.
5. Participants' management of their own health and care is measured using the Patient Activation Measure (PAM) at baseline, post-intervention and 6 months post-intervention.
6. Health utility in terms of capability including aspects of wellbeing is measured using the ICEpop CAPability measure for Adults (ICECAP-A) at baseline, post-intervention and 6 months post-intervention.
7. Use of health, social care, participant, and broader societal resources is measured using a bespoke Resource Use Questionnaire at baseline, post-intervention and 6 months post-intervention.

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bespoke Resource Use Questionnaire at baseline, 15 weeks post-randomisation and 40 weeks post-randomisation

Overall study start date
01/07/2018

Completion date
30/06/2020

Eligibility

Key inclusion criteria
1. Parent carers of children with special educational needs and disabilities aged up to 25 years consistent with the current UK Department of Health and Department of Education Special Educational Needs & Disability (SEND) legislation and The Children's Act 2014
2. Willing and able to attend the programme group meeting sessions on arranged dates/times subject to allocation

Participant type(s)
Carer

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 96; UK Sample Size: 96

Total final enrolment
93

Key exclusion criteria
Not able to communicate in English. This is necessary in the feasibility study because the programme has not yet been translated into other languages and SW England is not ethnically diverse. This criterion will not be used for the national definitive trial as the trialists can translate the programme and purposively recruit in black and minority ethnic communities, for instance in collaboration with Include Me TOO (www.includemetoo.org.uk).

Date of first enrolment
29/10/2018

Date of final enrolment
20/05/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Exeter Medical School
South Cloisters, St Luke's Campus
University of Exeter
Exeter
United Kingdom
EX1 2LU

Sponsor information

Organisation
University of Exeter

Sponsor details
Research Ethics and Governance Office
Lafrowda House
St Germans Road
Exeter
England
United Kingdom
EX4 4PY

Sponsor type
University/education

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0317-20044

Funder Name

National Lottery Community Fund

Alternative Name(s)
BIG

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed, open access, academic journal.

Intention to publish date
31/07/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository: Open Research Exeter (ORE) - https://ore.exeter.ac.uk /repository/. Type of data that will be shared: anonymised dataset. When the data will become available and for how long: June 2021; permanently. Data will be shared on reasonable request to the chief investigator.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/11/2019	05/12/2019	Yes	No
Results article	results	23/07/2021	26/07/2021	Yes	No
Results article		23/07/2021	29/07/2021	Yes	No
Results article	process evaluation	25/08/2021	27/08/2021	Yes	No