ISRCTN11382067 https://doi.org/10.1186/ISRCTN11382067

A group interpersonal psychotherapy intervention for caregivers of children with nodding syndrome to improve the mental health of both

Submission date
27/05/2016

Recruitment status
No longer recruiting

Registration date
08/06/2016

Overall study status
Completed

Last Edited
10/07/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Nodding syndrome (NS) is a recent, little-known disease that occurs only in children and only in small regions in South Sudan, Tanzania and northern Uganda. It was first described in 1962. The disease causes affected children to have so-called nodding seizures, often triggered by eating or when they feel cold. The seizures are short lived and stop once the trigger is removed (i.e. they stop eating or become warm again). Over time, the condition leads to a permanent stunting of growth and cognitive development and leads to mental handicap. It is not known what causes the disease, but it may be associated with being infested with a parasitic worm called Onchocerca volvulus. There is no known cure for the disease and so the available treatments concentrate on alleviating symptoms; this includes the taking if anticonvulsant drugs, for example phenobarbitol. Looking after children with NS can cause significant strain on the family looking after them and it can cause the mental health of both sufferers and their caregivers (for example, parents).The study aims to design and investigate the effectiveness of a family based, group interpersonal psychotherapy treatment (IPT-F) for caregivers of patients with Nodding Syndrome (NS) on the mental health of both the caregivers and patients compared to usual care (provided for in the national NS response plan).

Who can participate?
Adults (aged at least 18) caring for a child with NS.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 are allocated to the control group and are given usual care. Those in group 2 are allocated to the intervention group. Participants in this group take part in interviews and group discussions with other caregivers. The information gained from these is then used to help design the intervention. The IPT-F intervention will be tested in Pader district, northern Uganda and involves one and a half hour group sessions with caregivers held weekly over a period of 12 weeks. It is delivered by trained village health team members who are supervised by trained health workers from the local health

facility. All participants are then followed up during the course of a year to see what affect the intervention has had on their mental wellbeing.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Makerere University School of Public Health, Makerere University (Uganda)

When is the study starting and how long is it expected to run for?
April 2013 to September 2014

Who is funding the study?
Grand Challenges Canada (Canada)

Who is the main contact?
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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
S4 0232-01

Study information

Scientific Title
Effectiveness of a family based group interpersonal psychotherapy intervention (IPT-F) for caregivers of children with nodding syndrome to improve the mental health of both in comparison to usual care

Acronym
IPT-F

Study objectives
In comparison to the control, the culturally sensitive IPT-F intervention will alleviate psychological distress symptoms and improve the mental health of caregivers leading to improved child-parent relationships and mental health of the children with Nodding syndrome (NS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Makerere University College Of Health Sciences, School Of Public Health. Higher Degrees Research and Ethics Committee, 14/06/2013, ref: IRB00011353

Study design
Single centre quasi experimental (intervention cohort) study design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Common mental disorders

Interventions
There are two arms in the trial; intervention and control. To obtain the participants in the intervention arm, caregivers are consecutively selected based on updated lists of caregivers from the local health facility NS (Nodding syndrome) register at Atanga Health centre and from Village Health Team (VHT) members resident in selected study parishes of Atanga sub-county. The participants for the control arm will be randomly chosen from an updated list of caregivers resident in selected study parishes in Awere sub-county.

The group interpersonal psychotherapy intervention (IPT-F) will involve weekly group sessions each lasting 1 and a half hours delivered by trained village health team (VHT) members for a period of 12 weeks. The VHT members will be supervised by trained health workers from the local health facility.

Caregivers in the control parishes will access the usual care as provided for in the national response plan for NS.The national response plan for NS includes health education about NS for affected communities, management of patients with NS , caregiver education and counselling at health facilities and designated treatment centres, outreach clinics and home visits to families affected by the syndrome.

Patients in both study arms will continue to receive the usual care during and after the intervention period.

The activities conducted during each of the 12 IPT-F weekly sessions depends on which session it is in the 12 week schedule.
During the first phase (sessions 1 and 2), the facilitator:
1. Helps group members develop rapport among themselves, feel comfortable in the group so that they can talk about how they feel and what is happening in their lives
2. Explains that everyone in the group has depression and can help one another
3. Explains that because of depression they may not feel that they can do as much in their lives as they had in the past, but that as they feel better they'll get back to their usual ways
4. Explains what will happen during the group sessions
5. Reviews everyone's depression symptoms using the translated version of primary health questionnaire-version 9.
6. Reminds each one of their particular problem areas and the connection to depression symptoms.
7. Prompts group members to talk about the interpersonal problem that is triggering the depression, and finds out how the person has been dealing with the problem during the previous week

During the middle phase (sessions 3-10) the facilitator:
8. Continues to make group members feel comfortable within the group and aims at ensuring that all members have an opportunity to talk during the session
9. Links each person's depression symptoms to current life problem
10. Helps members listen to each other and tries to get each one of them to offer ideas that could be useful to another group member in dealing with a problem
11. Helps members act in a caring way towards one other
12. Continues to encourage members to be hopeful about realising changes in their life that will make them feel better

During the termination phase (sessions 11-12), the facilitator encourages each member:
13. To talk about any life changes and their feelings about these changes
14. To talk about their depression: what symptoms have gone and what symptoms remain
15. To talk about what worries them about the future
16. To talk about what has not changed in their life and how they feel about that.and
17. To talk about how they feel about the cessation of the group meetings

Intervention Type
Behavioural

Primary outcome measure
Proportion of caregivers with improved mental health status (a decrease in proportion of caregivers with depression) after one year follow up, assessed using mini plus neuropsychiatric interview (depression module)

Secondary outcome measures
1. The proportion of caregivers with:
1.1. Generalised anxiety disorder (GAD) measured using mini plus neuropsychiatric interview (GAD module.
1.2. Post traumatic stress disorder (PTSD) measured using mini plus neuropsychiatric interview (PTSD module)
1.3. A high risk of suicide measured using mini plus neuropsychiatric interview(suicide module)
1.4. High levels of psychological distress measured using the self-report questionnaire
1.5. Low levels of functioning measured using the assessment of functioning questionnaire
1.6. Low levels of social support measured using the social support scale
1.7. High levels of stigma measured using the devaluation of consumer's scale

2. Proportion of affected children with:
2.1. An abnormal total difficulties score measured using the strengths and difficulties questionnaire
2.2. High parent attachment scores measured using the inventory of parent and peer attachment questionnaire
2.3. Depression measured using the depression self-rating scale
2.4. Separation anxiety disorder measured using the mini kid neuropsychiatric interview
2.5. Generalised anxiety disorder measured using the mini kid neuropsychiatric interview
2.6. Attention deficit hyperactivity disorder measured using the mini kid neuropsychiatric interview
2.7. Psychological trauma measured using the revised child impact of events scale

Overall study start date
01/04/2013

Completion date
30/09/2014

Eligibility

Key inclusion criteria
1. A caregiver will be included in the study if she/he is an adult ≥18 years of age
2. Is living in the selected study parishes
3. Is a primary caregiver for a patient (child/adolescent) with Nodding Syndrome
4. Gives informed written consent
5. Gives assent for and presents with one of their NS-affected children for assessment

Participant type(s)
Mixed

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
To estimate the sample size for our study, we assumed a 55% prevalence of depression among people in northern Uganda and estimated that the IPT-F would reduce depression in the caregivers by 50% as shown in a similar study in Uganda. With a level of precision of 5% and with a power of 80%, the sample size for each arm is calculated to be 57. STATA command: sampsi 0.55 0.275, alpha (0.05) power (.80). However with an expected attrition of up to 15% of the caregivers during the study, the total sample size is estimated to be 132 people, 66 from each arm.

Total final enrolment
142

Key exclusion criteria
1. Is severely ill and unable to participate in the study
2. Does not give informed written consent to participate in the study

Date of first enrolment
02/09/2013

Date of final enrolment
15/09/2013

Locations

Countries of recruitment
Uganda

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Sponsor type
University/education

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Sponsor type
Research council

Funder(s)

Funder type
Government

Funder Name
Grand Challenges Canada

Alternative Name(s)
Grands Défis Canada, GCC

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
Canada

Results and Publications

Publication and dissemination plan
1. Dissemination of study results at a meeting with caregivers of children with NS, local leaders and the study team in the study area
2. Publications on formative study, adaptation of the IPT-F intervention and effectiveness of the IPT-F over a 3 year period

Intention to publish date
06/06/2017

Individual participant data (IPD) sharing plan

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		28/06/2018		Yes	No
Results article		15/02/2018	10/07/2023	Yes	No