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Evaluation of a pain management programme for adolescent girls and young women with intellectual disabilities who experience menstrual pain

Submission date
21/05/2013

Recruitment status
No longer recruiting

Registration date
12/06/2013

Overall study status
Completed

Last Edited
10/09/2014

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Pain management is largely ignored by people with intellectual disability. Pain management programmes are not routinely offered to such people who experience menstrual pain. There is ample evidence that cognitive behaviour therapy (CBT) (a talking therapy) can be used for pain management in the general population. The aim of this study is to evaluate a group-based CBT programme for menstrual pain management in adolescent girls and young women with intellectual disabilities and examine which elements of the programme appear to work for this population.

Who can participate?
Participants must be female and aged 12 to 30 years. They must have a diagnosis of a mild or moderate intellectual disability, have started menstruation and experience pain symptoms in the days before or during menstruation. Speech must be their primary means of communication.

What does the study involve?
In total, there will be 36 to 48 participants involved in the research. Participants will be divided into two groups, a treatment group (18 24 participants) and a matched control group (treatment-as-usual) (18 24 participants). The treatment group will then be divided into 3 groups for participation in the menstrual pain management programme with a maximum of 8 participants in each group. Each treatment group will be matched with a treatment-as-usual group, receiving usual care in terms of management of menstrual pain.
Participants in the treatment group will be asked to participate in a 12 week pain management programme. This will be delivered in groups, in a location which is suitable and convenient to participants and at a convenient time. Groups will take place on a weekly basis and each session will approximately last for 45 minutes.
Participants will be assessed at the beginning of the study to obtain information regarding their

reported levels of pain, the impact of pain on their lives, pain knowledge and pain coping. These measures will be completed at the end of the programme and at three months after the programme.

What are the possible benefits and risks of participating?
The study is intended to benefit participants and third parties including parents, family members and staff members working with these individuals. By teaching young women with intellectual disabilities strategies to manage their menstrual pain, it is predicted that this research will have a positive effect on their mood, quality of life, attendance at school, training and/or work and social participation. These changes are likely to have a positive and beneficial effect on interpersonal relationships with parents, family members, peers and others. In the long-term, there are likely to be positive implications for the local community. Psychological discomfort in the form of social embarrassment may be experienced by some participants, in discussing the topic of menstrual pain in a group setting. The following precautions will be taken to minimise any potential harm to participants:
controlling the number of participants in each group (small groups)
discussing the potential for embarrassment with participants and offering support in managing this if required
careful attention to establishing rapport between group participants with ice breakers before introducing sensitive words/topics
sensitive discussion of words/topics which some participants might find discomforting
informing participants that they are free to withdraw from the study at any stage and without consequence

Where is the study run from?
This study is run from the Brothers of Charity Services, 10 Church Hill, Ballinasloe, Galway, Ireland. There are likely to be at least three centres taking part in this trial and these are:
Ard Scoil Mhuire Secondary School, Mackney, Ballinasloe, Co. Galway, Ireland
Lakeview School, Renmore, Galway, Ireland
TOPE Centre, Poolboy, Ballinasloe, Co. Galway, Ireland

When is the study starting and how long is it expected to run for?
The start date of the study is 01/09/2012 and it is expected to last for approximately 18 months. The trial will be recruiting participants, in phases, for approximately 12 months.

Who is funding the study?
The researcher, Susan Kennedy, will be paying the costs that the trial incurs during its lifecycle.

Who is the main contact?
Ms Susan Kennedy
Email: susankennedy@galway.brothersofcharity.ie

Contact information

Type(s)
Scientific

Contact name
Ms Susan Kennedy

Contact details

Senior Clinical Psychologist
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-

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Evaluation of a mixed methods matched controlled clinical trial of a group based cognitive behaviour therapy programme for menstrual pain management in adolescent girls and young women with intellectual disabilities

Study objectives
1. Participation in the menstrual pain management group will result in a reduction in ratings of pain intensity by participants and their parents and this will be maintained at 3 month follow-up.
2. Participation in the menstrual pain management group will result in an increase in participants ratings of pain self-efficacy, pain knowledge and pain coping strategies and this will be maintained at 3 month follow-up.
3. Participants whose parents score highly on pain-catastrophizing will experience greater pain intensity and greater pain impact on quality of life.
4. Participants in the menstrual pain management group will adopt more behavioural than cognitive coping strategies to manage their menstrual pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. City University London Psychology Department Research & Ethics Committee, Ethics approval granted on 16/05/2012, Ref: PSYETH 11/12 026
2. Brothers of Charity Services Research Ethics Committee, Ethics approval granted on 25/06 /2012

Study design
Interventional multiple centre mixed methods matched controlled clinical trial

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
Menstrual pain management in the intellectual disability population

Interventions
This is an intervention study across multiple centres with individuals receiving support services from one intellectual disability provider.
The intervention received by the treatment group is called menstrual pain management group and the intervention received by the control group is treatment-as-usual.
The menstrual pain management group intervention comprises 12 group sessions, delivered once a week, for approximately 45 minutes. The topics covered over the course of the group are:

Week 1 Understanding Menstrual Pain
Week 2 Relaxation (Deep Breathing)
Week 3 Relaxation (Progressive Muscular Relaxation)
Week 4 Relaxation (Visualisation)
Week 5 Exercise
Week 6 Distraction Techniques
Week 7 How your thoughts make you feel
Week 8 Challenging Negative Thoughts
Week 9 Positive Thinking and Coping Self-Talk
Week 10 Problem Solving
Week 11 Medication
Week 12 Self Management

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Pain Coping Questionnaire
Assessment of strategies used to cope with pain in four hypothetical situations. Pain coping measured pre-intervention (baseline), 5 weeks from baseline, 9 weeks from baseline, post-intervention (3 months from baseline) and at follow-up (3 months from administration of post-intervention measures).

Secondary outcome measures

Participant Measures:
1. Pain Rating Scale
Pain rating measured using a Visual Analogue Scale (VAS) score where 0 = no pain, 10 = unbearable pain. Pain rating measured pre-intervention (baseline), post-intervention (3 months from baseline) and at follow-up (3 months from administration of post-intervention measures).
2. Pain Impact Scale
Modified from the Brief Pain Inventory Short Form (Cleveland, 1991). Pain impact measured using a Likert Rating Scale where 0 = no impact, 10 = significant impact. Pain impact measured pre-intervention (baseline), post-intervention (3 months from baseline) and at follow-up (3 months from administration of post-intervention measures).
3. Pain Self-Efficacy Scale
Modified from the Pain Self-Efficacy Scale for Children (Bursch, Tsao, Meldrum & Zelter, 2006). Pain self-efficacy measured using a Likert Rating Scale where 1 = very sure, 5 = very unsure. Pain self-efficacy measured pre-intervention (baseline), post-intervention (3 months from baseline) and at follow-up (3 months from administration of post-intervention measures).
4. Pain Knowledge Questionnaire
Pain knowledge measured using a 7 item multiple choice questionnaire. Pain knowledge measured pre-intervention (baseline), 5 weeks from baseline, 9 weeks from baseline, post-intervention (3 months from baseline) and at follow-up (3 months from administration of post-intervention measures).
5. Pain Coping Strategies Questionnaire
Assessment of strategies used to cope with pain. Pain coping measured pre-intervention (baseline), post-intervention (3 months from baseline) and at follow-up (3 months from administration of post-intervention measures).

Parent Measures (Pre- and post-intervention and at 3 month follow-up):
1. Background Information Questionnaire
Questionnaire seeking demographic information on participants regarding age at onset of menstruation, frequency and duration of menstruation, symptoms experienced during menstruation, gynaecological / medical history, medications used and treatments received.
2. Pain Rating Scale
Pain measured using a Visual Analogue Scale (VAS) score where 0 = no pain, 10 = unbearable pain. Pain rating measured pre-intervention (baseline), post-intervention (3 months from baseline) and at follow-up (3 months from administration of post-intervention measures).
3. Pain Impact Scale
Modified from the Brief Pain Inventory Short Form (Cleveland, 1991). Pain impact measured using a Likert Rating Scale where 0 = no impact, 10 = significant impact. Pain impact measured pre-intervention (baseline), post-intervention (3 months from baseline) and at follow-up (3 months from administration of post-intervention measures).
4. Pain Catastrophizing Scale
Assessment of parents thoughts and feelings when there child is in pain assessed using a 13 item Rating Scale. Response options to statements are: not at all (disagree), mildly (agree), moderately (agree), severely (agree) and extremely (agree).

Pre- and post-intervention focus groups to examine design programme content, evaluate delivery and participation and obtain suggestions to enhance the programme.

Overall study start date

01/09/2012

Completion date
31/03/2014

Eligibility

Key inclusion criteria
Females aged between 12 and 30 years of age who:
1. Attend secondary school or an adult training centre
2. Have a diagnosis of mild moderate intellectual disability
3. Have commenced menstruation
4. Experience pain symptoms in the days preceding or during menstruation
5. Have speech as their primary means of communication

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
The target number of participants is 36 48. Participants will be divided into two groups, a treatment group (18 24 participants) and a matched control group (18 24 participants).

Key exclusion criteria
Females who:
1. Are younger than 12 years of age
2. Are over 30 years of age
3. Have a diagnosis of severe or profound intellectual disability as research indicates that cognitive-behavioural approaches work best with individuals with mild and moderate intellectual disabilities.
4. Do not have a diagnosis of intellectual disability as the study seeks to look at the issue of menstrual pain management in individuals with an intellectual disability
5. Have not commenced menstruation
6. Do not experience menstrual pain
7. Communicate via non-verbal strategies
Participants will not be excluded from participating in this research on the basis of ethnicity, race, sexuality, religion or any other socio-cultural factor.

Date of first enrolment
01/09/2012

Date of final enrolment
31/03/2014

Locations

Countries of recruitment

Ireland

Study participating centre
Senior Clinical Psychologist
Galway
Ireland
-

Sponsor information

Organisation
City University London (UK)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/04489at23

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Ireland)

Funder Name
Brothers of Charity Services, Psychology Department (Ireland) - Contribution towards the cost of registering the study

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/09/2014		Yes	No