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Brief interventions to reduce risky drinking in parents of children referred to children's social care

Submission date
19/09/2016

Recruitment status
No longer recruiting

Registration date
16/11/2016

Overall study status
Completed

Last Edited
09/01/2024

Condition category
Mental and Behavioural Disorders

[X] 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
Many children in the UK live with a parent who drinks alcohol in a way that can be harmful to both the parent and the child. Most of these parents drink in a way that increases the risk of harm rather than dependently. These parents are often not identified by professionals and the parent may not know they are experiencing alcohol-related problems. Brief alcohol interventions (short programs designed to tackle problems relating to alcohol) have been found to be effective at reducing risky alcohol use in a primary care setting. However, it is not currently known if these interventions are effective in social care settings or with parents whose children have been referred to children's social care. This study will adapt existing brief alcohol interventions to make them relevant to parents and investigate whether social care practitioners within children's services can recruit parents into the study and deliver a brief intervention, aimed at reducing risky drinking in parents of children where there is a concern for the child's wellbeing. The study will also find out if parents participating in the study can be followed-up after they receive the intervention.

Who can participate?
Parents of children who have been referred to children's social care due to concerns regarding the well-being of the child who screen positive for risky alcohol use.

What does the study involve?
In the first stage of the study parents, social care practitioners and drug and alcohol workers are consulted to adapt existing brief alcohol interventions to make them relevant to parents.
In the second stage of the study, social care practitioners are randomly allocated to one of three groups. Participating parents who are identified by social care practitioners as drinking alcohol in a risky way receive either a healthy lifestyle leaflet, 10-30 minutes of alcohol advice provided by the social care practitioner or 10-30 minutes of alcohol advice plus a referral to an alcohol treatment service for brief alcohol counseling (one or two sessions). These parents are asked to complete a questionnaire when they enter the trial and 6 and 12 months later. In the final stage of the study, a small group of parents and practitioners are invited to talk to the researcher about their experience of participating in the trial.

What are the possible benefits and risks of participating?
Some parents may find it helpful to receive alcohol advice or talk to a practitioner about their alcohol. All participating parents will receive £10 voucher (at each of the three stages) to reimburse them for their time. The main risk to participating parents and practitioners is the burden of time.

Where is the study run from?
1. Newcastle City Council (UK)
2. Durham County Council (UK)
3. North Tyneside Council (UK)

When is the study starting and how long is it expected to run for?
January 2015 to June 2022 (updated 24/02/2021, previously: June 2019)

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Ruth McGovern
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BH138087

Study information

Scientific Title
PAReNTS (Promoting Alcohol Reduction in Non-Treatment Seeking Parents): Brief interventions to reduce hazardous and harmful drinking in parents of children referred to children's social care: a pilot feasibility study

Acronym
PAReNTS

Study objectives
The aim of this study is to assess the feasibility and acceptability of the study intervention and trial procedures of a definitive three-arm multi-centre cluster randomised controlled trial (two alcohol interventions and control intervention; usual care plus the provision of a healthy lifestyles leaflet) to reduce risky drinking in parents whose child(ren) are referred to social care due to a well-being concern.

Ethics approval required
Old ethics approval format

Ethics approval(s)
HRA Social Care REC London, 02/11/2016, ref: 16/IEC08/0037

Study design
Three linked phases:
1. Formative study phase (intervention development)
2. Pilot feasibility cluster randomised controlled trial (cRCT)
3. Process evaluation

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Alcohol use disorders

Interventions
Formative study
Parents of children referred to children’s social care due to a wellbeing concern will be identified

by social care practitioners from their caseload in the research sites (Newcastle, Durham and North Tyneside). The sample will be chosen to ensure maximum variation with regards to gender, ethnicity, age of children, family composition and referral reason. After informed consent has been given, one-to-one qualitative interviews will be undertaken with a purposive sample of parents recruited from the children's social care. Interviews will continue until data saturation is reached; it is estimated that n=20 will be required. The interviews will explore beliefs around parental alcohol usage, helpful interventions and acceptable approaches. Key behavioural issues and motivational domains as well as the challenges that the intervention should address will be identified.

Focus groups will be held with social care practitioners (n=8) and drug and alcohol practitioners (n=8) within the research sites. The social care practitioners have key knowledge of the context of children's social care as well as many of the ethical issues which must inform intervention development. Drug and alcohol practitioners hold specialist knowledge relating to engaging and intervening with alcohol users which will also benefit intervention development. Informed consent will be obtained from all participants.

The data from the formative study will be used to inform the development of brief alcohol interventions for risky drinking parents. These interventions will be used in a feasibility trial as discussed below. The parents' role within the overall study will end at this stage.

Feasibility randomised controlled trial:
All eligible parents of children referred into children's social care in the study sites will be screened by their social care practitioners for risky drinking. Social care practitioners will administer the AUDIT-C screening tool, which measures alcohol consumption. Those screening positive on the AUDIT-C (an AUDIT score of ≥5) will be invited to participate in the 3-arm trial by the social care practitioner. Participating parents will complete a baseline questionnaire and receive one of three interventions. The unit of randomisation is the social care practitioner.

Control: Participants receive a healthy lifestyle leaflet only.

Brief alcohol intervention: The brief alcohol intervention will be 10-30 minutes in duration and will be delivered by the social care practitioners. Brief alcohol intervention seeks to raise awareness through the provision of personalised feedback following screening. Advice is provided on recommended levels of use, the risks (to both the parent and the child) associated with the individual's specific pattern of drinking and practical steps on how to reduce drinking behavior and its adverse consequences. The approach includes normative comparison based upon social learning theory which assumes that individuals moderate their behaviour according to that of others around them. Participants will be encouraged to consider a reduction in alcohol consumption in order to reduce risk to both the parent and child.

Extended alcohol intervention: The extended alcohol intervention will be approximately 45 minutes in duration (and may include a further booster session). It will be delivered by a specialist alcohol practitioner. Extended alcohol intervention involves a patient-centered counseling technique, based upon motivational interviewing. Extended brief intervention introduces and evokes change by giving the patient the opportunity to explore their alcohol use and motivations and strategies for change. This approach will be adapted for delivery with parents involved in children's social care.

All participants who completed baseline questionnaires will be contacted by phone and letter /email at 6 and 12 months post recruitment to complete a follow-up questionnaire. The questionnaire will be administered in person or over the phone by the researcher or self-

completed via post, email or the web (depending upon participant preference). A purposive sample of participants who have indicated that they are willing to be contacted for a qualitative interview will be invited to participate in the process evaluation. The remaining participants will end their involvement in the trial after 12 month follow-up.

Process Evaluation:
Qualitative, semi-structured interviews will be conducted with a purposive sample of parents, social care practitioners and drug and alcohol practitioners who participated in the feasibility trial. The process evaluation aims to understand and document the key lessons learned from the PAReNTS trial (both the interventions and the trial processes) and to evaluate factors needed to deliver the intervention at scale. Interviews will explore a number of factors including: barriers and facilitators for implementation from parental and practitioner perspectives; issues relating to consent specific to the children's social care setting; burden of time; parental and social work experiences of intervention delivery and fidelity; training requirements for social care staff. Data collection will continue until data saturation is reached however it is estimated that n=20 parents and n=20 practitioners will be required. The involvement of the practitioner and parents will end on completion of the one-to-one interview.

Intervention Type
Behavioural

Primary outcome measure
Formative study:
1. Parents' beliefs around parental alcohol usage, helpful interventions and approaches is gathered though a qualitative interview prior to the commencement of the trial
2. Practitioner views and experiences of engaging and intervening with parents who drink alcohol is gathered through a focus group prior to the commencement of the trial

Feasibility randomised controlled trial
1. Recruitment rate is recorded as the number of eligible participant who consent to participate in the study
2. Retention rate is recorded as the number of participants who complete the follow-up questionnaire at 12 months

Process evaluation:
Participating parents and practitioners views and experiences of trial processes and interventions will be gathered in one-to-one interviews on completion of the trial.

Secondary outcome measures
Feasibility randomised controlled trial
Intervention fidelity is measured (using a-priori criteria) according to extent to which the intervention is delivered in-line with the manual.

Overall study start date
01/01/2015

Completion date
01/06/2022

Eligibility

Key inclusion criteria
1. Parents whose child is referred to children's social care due to concerns regarding the well-being of the child and are an active case
2. Screen positive for risky alcohol use i.e. scoring ≥5 on the AUDIT-C
3. Informed consent given

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants
180

Key exclusion criteria
1. Already in active treatment with drug and alcohol services
2. Parents of children on a child protection plan
3. Parents of children who are placed on an emergency protection order
4. Have severe, chronic or acute mental health problems or who are severely distressed
5. Unable to give informed consent in English

Date of first enrolment
01/03/2017

Date of final enrolment
28/02/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle City Council
Children's Social Care
Civic Centre
Barras Street
Newcastle upon Tyne
United Kingdom
NE1 8QH

Study participating centre
Durham County Council
Children's Services
County Hall
Durham
United Kingdom
DH1 5UQ

Study participating centre
North Tyneside Council
Children's Services
Colbalt Business Centre
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United Kingdom
NE27 0BY

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Sponsor type
University/education

ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
On completion of the study, data will be analysed and tabulated and a final study report prepared. This will be available from the NIHR and FUSE websites. It is planned to publish this study in peer review articles and to present data at national and international meetings. Results of the study will also be reported to the Sponsor and Funder. Publications will be shared with the TOC and funders. Individuals will not be identified from any study report. Individuals will not be identified from any study report. Participants will be informed about their treatment and their contribution to the study at the end of the study, including a lay summary of the results.

Intention to publish date
31/05/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Ruth McGovern (r.mcgovern@ncl.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	09/06/2018		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet			09/01/2024	No	Yes