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Investigating the clinical and cost-effectiveness of children's early self-care support in children with neurodisability

Submission date	Recruitment status	[X] Prospectively registered
19/11/2024	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/11/2024	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/11/2026	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Young people who have previously received therapy, parents of young children currently receiving therapy, and therapists have expressed the need for improvements in therapy. They collectively agree on the importance of better-supporting children who require assistance with independence and everyday activities, such as eating, drinking, dressing, mobility, and sleeping. It is crucial to help young children develop independence as early as possible. However, there is currently limited evidence and no national guidelines on the best methods to achieve this. This study aims to investigate whether CHESS (CHildren's Early Self-care Support) is more effective than the usual support provided by therapists. This will be done by comparing the CHESS system with the current self-care support system. The study will involve 40 NHS organisations, with half using the CHESS system and the other half continuing with their usual self-care support. A total of 960 parents will be asked to provide information about their children's self-care, health, and quality of life, as well as their own health and wellbeing. Additionally, data on the costs and resources spent on accessing and providing support will be collected. The effectiveness of CHESS will be evaluated several months after the study begins to determine if it improves self-care and is a cost-effective use of public funds. Interviews and focus groups with parents and therapists will be conducted to explore their experiences with CHESS and ensure the study runs smoothly. The study will also monitor any potential risks or harms associated with CHESS.

Who can participate?

Children aged 12 months to 4.5 years with neurodisability

What does the study involve?

Parents or carers will be asked to complete questionnaires about their and their child's health at the start of the study, six months later, and twelve months after the study begins. Additional questions about healthcare costs and travel will be asked nine months into the study. Families will continue attending their child's therapy appointments as usual, with no extra visits required, and the therapy provided will not change.

What are the possible benefits and risks of participating?
There is no certainty that participants will gain direct benefits from the study. However, by participating, families will contribute to improving therapy services for young children. The study's findings will help plan effective NHS therapy services in the future. There are no anticipated risks for participants, though the time commitment for completing questionnaires is a consideration. Efforts have been made to minimize and make this commitment as flexible as possible. Collecting information from parents is essential to determine the effectiveness of the therapy.

Where is the study run from?
The study is coordinated by Newcastle University (CI) and the University of Aberdeen (CTU).

When is the study starting and how long is it expected to run for?
February 2024 to January 2028

Who is funding the study?
NIHR Health Technology Assessment (HTA) Programme

Who is the main contact?
Prof Niina Kolehmainen (CI), CHESS@abdn.ac.uk (trial office)

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Additional identifiers

Integrated Research Application System (IRAS)
331267

Central Portfolio Management System (CPMS)
57270

Study information

Scientific Title
CHESS: Investigating the clinical and cost-effectiveness of CHildren's Early Self-care Support in children with neurodisability: the cluster randomised controlled trial

Acronym
CHESS

Study objectives
Caring for oneself (self-care) is essential to survival. It encompasses independence (e.g. learning to feed oneself) and involvement in self-care situations (e.g. making choices and coping with mealtimes with others). It is estimated 3-4% of children in the UK have a neurodisability, with self-care problems that are both significant and common. While many can achieve self-care levels close to their typically developing peers this requires significant parent and therapy support. There is currently little evidence of effective self-care interventions, no national guidelines, and no cost-effectiveness evidence for commissioners. Parent, young person, and multidisciplinary professional consensus is that additional evidence is urgently needed.

The aim is to determine the clinical and cost-effectiveness of CHESS in young children with neurodisability compared to usual care. The objectives are to:
1. Determine the clinical and cost-effectiveness of CHESS compared with usual care, on self-care skills and involvement for young children with neurodisability, measured at 6 and 12 months after cluster randomisation.
2. Estimate the relative efficiency of CHESS compared with usual care, in terms of self-care skills

and involvement in young children with neurodisability.
3. Conduct an embedded evaluation of recruitment, intervention acceptability, and implementation to support trial delivery.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 31/10/2024, North East – Newcastle and North Tyneside 1 (2nd Floor, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8384; newcastlenorthtyneside1.rec@hra.nhs.uk), ref: 24/NE/0162

Primary study design
Interventional

Study design
Two-arm pragmatic cluster-randomized controlled trial across 40 clusters with embedded economic and process evaluations

Study type(s)
Quality of life, Treatment

Health condition(s) or problem(s) studied
Investigating the clinical and cost-effectiveness of self-care support in children with neurodisability

Interventions
The trial will evaluate CHESS (CHildren's Early Self-care Support), a multi-component behaviour change intervention, compared to usual children's community NHS therapy (occupational therapy, physiotherapy, speech and language therapy) for self-care. In CHESS, the therapists and families will receive materials and training about communicating self-care priorities, nurturing helpful and enjoyable self-care routines, overcoming barriers, and developing children's movement. In usual care, the therapists and families will do what they would have done if no trial was taking place.

CHESS will include children (from age 12 months to 4 years 6 months) with neurodisability where the need for self-care support is confirmed, together with one of the child's parents or carers. Neurodisability covers a range of children typically seen in paediatric community/outpatient care.

CHESS is a 2-arm pragmatic cluster randomised controlled trial across 40 NHS sites (paediatric community and outpatient NHS therapy services).

As CHESS is a cluster randomised trial, all eligible children within a cluster will receive the treatment allocated for their site; i.e. there is no random allocation of individual children.

Eligible children (and their parents) will be identified from their local NHS caseloads at each site (cluster) and a random subset will be asked to participate in the data collection part of the CHESS trial. The approach to recruiting individual families will come from the local clinical team - either by post, phone or in person.

The recruitment materials will specifically invite the parent to participate in the trial data collection - making it clear that their decision to participate in data collection will have no impact, either way, on their child's treatment allocation or options. It will invite them to contact the agreed point of recruitment to discuss participation in the trial, and if willing, to sign the consent form and complete the baseline questionnaire. It will also provide information that if the parent is willing, the research team will obtain clinical case note data on the child's diagnoses, development and treatment(s) provided.

Parents will be invited to indicate their willingness to discuss participation by telephoning, texting or emailing the trial team, by returning a pre-prepared expression of interest slip in a prepaid envelope, or by verbally indicating their willingness to a member of the local cluster team/service.

Sampled parents who have not made contact to discuss their potential participation, will be followed up by a first and second reminder (telephone, postal or in person where applicable) a week and two weeks later, respectively. If the parent/carer volunteers a reason for not participating, this will be recorded. After two reminder attempts, no further contact about participation will be made.

Informed consent, for participation in the trial data collection, will be sought from parents. For each child, a parent (primary adult caregiver) will be asked to consent to: data collection; follow-up; and contact in the future about this and other relevant research. The informed consent will be received in person, by post (with the informed consent discussion happening over the phone /video call), electronically (eConsent) or verbally (audio-recorded), in line with local and parent preference. Parents will also be asked to complete a baseline questionnaire. Contact details of participating parents (including postal address, email, home and mobile number) and their contact preferences (email, phone call, post, and in-person visits) will also be collected.

Given the age group of the children (from 12 months to under 4 years and 6 months old), child-specific information leaflets/posters will not be used as the child will not be asked to agree to participate in CHESS, but instead are asking the parents to contribute to data collection. All children attending a cluster site will receive the same care (according to the site randomisation allocation) whether or not the parent agrees to participate in data collection for CHESS for their child. All participating children will be too young to provide informed consent, and no data will be directly collected from the children, therefore no assent related to the trial will be sought.

All children will continue to have a say in all clinical procedures in the context of the therapeutic relationship. This will be managed by the child's care provider.

Following consent of the sampled parents within a site. The site will be randomised to provide the CHESS intervention or their usual self-care support.

Parents and children in a site (cluster) which is providing their usual self-care support, will continue their care as usual at that site.

Parents of children within a site that is providing the CHESS intervention will receive the CHESS support package which consists of a minimum intervention cycle with:

o brief goal-setting (5-15min);

o at least one home visit (~60min) using related materials; and o an invitation to at least one movement play session (up to 90min).

The intervention can be tailored to children of varied development and abilities.

All parents participating in the data collection component will be asked to complete a questionnaire at 6, 9 and 12 months after the site has been randomised. These can be completed at home using their preferred method of completion (phone, post, email or in-person). First reminders will be issued (according to their stated contact preference) if no response to questionnaires has been received. Up to two follow-up reminders (by telephone) will be attempted but if there is no response by telephone, a final reminder will be sent by email, text or post (according to contact preference).

Questionnaires will be administered to all parents who consented to data collection whether or not the child has received the intervention unless they have opted out of questionnaire follow-up. This means that consented parents and children who have not received their allocated treatment, have received the non-allocated treatment, or where therapy has been discontinued, will continue to be followed up in the study.

Participants remain in the data collection part of the trial unless they choose to withdraw consent. Participants are free to withdraw from the trial at any timepoint. All status changes, except for complete withdrawal of consent, mean the participant is still followed up for all trial outcomes wherever possible. All data collected up to the point of complete withdrawal is retained and used in the analysis.

An embedded process evaluation component is also included: a mixed-methods process evaluation will be conducted, involving a range of stakeholders to further develop recruitment and trial processes, with particular attention to inclusion and diversity; further specify the description of current care; and understand the determinants of successful provision and outcomes of CHESS, including potential subgroup differences.

This process evaluation will draw on interviews with parents who accept and who decline participation in data collection, interviews and focus groups with local cluster staff, written feedback from local cluster staff, as well as non-participant observations of the management and delivery of CHESS by local cluster staff.

Intervention Type
Behavioural

Primary outcome(s)
The clinical effectiveness of CHESS compared with usual care, on self-care skills and involvement for young children with neurodisability will be measured using parent-reported Pediatric Evaluation of Disability Computer Adaptive Testing (PEDI-CAT) Activities Of Daily Living module 12 months after the start of intervention

Key secondary outcome(s)
1. Self-care involvement within dynamic child-caregiver interactions, with a focus on the child's agency, comfort, stress, and psychological safety, measured using the Vineland-3 coping skills subdomain at baseline, 6 and 12 months
2. Child health-related quality of life will be measured using the Child Health Utility instrument (CHU9D) at baseline, 6 and 12 months (a version of this has been developed suitable for preschool children)
3. Caregiver health capturing health impacts on carers and allow calculation of QALYs will be measured using the generic health survey Short Form-36 version 2 (SF-36v2) at baseline, 6 and

12 months
5. Carer care-related quality of life will be measured using the ICECAP Carer Experience Scale (CES). Chosen to capture aspects of carer quality of life beyond health likely to be affected by the intervention at baseline, 6 and 12 months
6. Potential risks and harms, including physical injury for the child and parent and other potential harms, measured using data identified via the harms reporting process and process evaluation
8. Satisfaction with treatment measured using the 12-month questionnaire and process evaluation
9. Health and social care service use measured using a Service Use Questionnaire (SUQ) at baseline, 6 and 12 months
10. Cost for carers/families for accessing services and purchased care measured using a Time and Travel Questionnaire (TTQ) at 9 months
11. An embedded evaluation of recruitment, intervention acceptability, and implementation to support trial delivery, will be conducted through process evaluation interviews with parents and site staff of the study process and acceptability (throughout the study)

Completion date
31/01/2028

Eligibility

Key inclusion criteria
1. Any child with neurodisability
2. Age at least 12 months and not older than 4 years 6 months on the date of sampling
3. Seen by at least one paediatric community/outpatient therapy service
4. Where self-care support is indicated
5. Where the family and therapist agree on a need for self-care intervention
6. Who has been randomly sampled for data collection from the participating therapists' caseloads
7. Whose parent is willing to consent to data collection and comply with study procedures

No restriction is placed on child mobility, cognitive, or communication capacities. The sample is expected to include a mix of children across these capacities due to the nature of caseloads and random sampling.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 Months

Upper age limit
54 Months

Sex

All

Total final enrolment
0

Key exclusion criteria
1. Children with no neurodisability
2. Children with only sensory impairment (e.g. visual, hearing)
3. Children with a degenerative condition(s)
4. Children with no clear self-care problems or goals
5. Children receiving one-off advice and discharge only
6. Children who are hospitalised or in end-of-life care
7. Children with a sibling already participating in the CHESS trial

Date of first enrolment
01/03/2025

Date of final enrolment
31/05/2027

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Sheffield Children's Hospital
Western Bank
Sheffield
England
S10 2TH

Sponsor information

Organisation
Sheffield Children's NHS Foundation Trust

ROR

https://ror.org/02md8hv62

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be stored in a non-publicly available repository https://w3.abdn.ac.uk/hsru/CHESS/Login/login.aspx.

Data collected during the research is kept strictly confidential and accessed only by members of the trial team. Data may be looked at by individuals from the Sponsor organisation or NHS clusters where it is relevant to the participant taking part in this trial. Consent regarding data storage and access will be obtained from all participants.

The CI and trial staff involved with this project will comply with the requirements of the General Data Protection Regulations (GDPR) and the Data Protection Act 2018. The HRA recommended wording to fulfil transparency requirements under the GDPR for health and care research has been included in the PIL.

Trial staff based at CHaRT in Scotland will also adhere to the current version of the NHS Scotland Code of Practice on Protecting Patient Confidentiality. CHaRT is a fully registered Clinical Trials Unit with particular expertise in running multicentre RCTs. The trial will be run under the auspices of CHaRT, University of Aberdeen. This aids compliance with Research Governance and the principles of GCP and provides centralised trial administration, database support and statistical analyses. CHaRT SOPs will be followed.

Access to collated participant data will be restricted to the CI and appropriate trial staff.

Computers used to collate the data will have limited access measures via usernames and passwords.

Remote access to the network will be subject to robust authentication, and VPN (Virtual Private Network) connections to the network are only permitted for authorised users, ensuring that use is authenticated, and data is encrypted during transit across the network.
No personal data will be downloaded or stored on local hard drives. All data input/access will be via the VPN and/or secure website.

Published results will not contain any personal data that could allow identification of individual participants.

The CHaRT senior IT development manager (in collaboration with the CI) manages access rights to the data set. Participants are allocated an individual trial number which is used to identify questionnaires and case report forms.

The team anticipate that anonymised trial data may be shared with other researchers to enable international prospective meta-analyses.

Data will be collected and stored in compliance with the local standard operating procedures (i. e. participating sites' SOPs, CHaRT CTU SOPs, and collaborating institutions' SOPs).
Clinical data will be collected on hardcopy CRF forms. These clinical data forms will then be input into the bespoke study database by the designated team members working in each recruitment cluster using a secure, electronic, web-based data capture system. If members of the study team prefer to carry out direct data entry into the study database (i.e. not complete hard copy CRFs), this will be acceptable and the electronic data capture will be the source data.
The designated team members working in each recruitment cluster will enter data from questionnaires completed at the clinic, or return to the trial office to be entered there.

Questionnaires returned by post to the trial office will be entered there. Staff in the trial office will work closely with local team members to ensure that the data are as complete and accurate as possible. Extensive range and consistency checks will further enhance the quality of the data. Responsibilities for archiving are documented in the co-sponsorship / site agreement.

The team intend to follow up with the whole cohort for 12 months. All essential data and documents (electronic and hard copy) will be retained for at least 10 years after the close of trial according to funder requirements and relevant Sponsor and CHaRT archiving SOPs. It is anticipated, that consent will be sought to allow collection of longer-term data on health resource usage. Documents will be reviewed by CI before being destroyed. Electronic data will be archived by UoA.

Baseline and outcome data will be described using summary statistics, by treatment group. All analyses will be based on the intention-to-treat principle. The primary outcome will be analysed using repeated measures mixed effects linear model extended for cluster randomised trials that include a random effect for cluster and as well as participant. Models will include a fixed effect for treatment, nominal time, and the baseline outcome score. Treatment effects will be estimated at each time point using a treatment-by-time interaction: the primary measurement time point is 12 months after recruitment into the trial. The primary analysis will use an unstructured time and covariance structure, which gives unbiased treatment effects when outcome data are missing at random (MAR). A MAR mechanism is unlikely to be the case in this population, and the team will explore the impact of missing data using pattern mixture models

under missing not random assumptions using models for repeated measures data in cluster randomised trials.

Secondary outcomes will be analysed similarly, with generalised linear models appropriate for the distribution of the outcome. All treatment effects will be presented using 95% confidence intervals. The team will report tables disaggregated by sex. Subgroup analysis to assess potential treatment-moderating effects of sex, mobility (using adapted GMFCS), and socioeconomic status will be carried out by modelling treatment-by-subgroup interactions. There is a planned interim efficacy analysis, and a final analysis after the last participant has finished follow-up.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			17/11/2026	No	No
Study website		11/11/2025	11/11/2025	No	Yes