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Version 2

Effectiveness of Adapted Behaviour Change Techniques for Adults with Learning Disabilities: A Comparative Study of Healthcare and Social Care Settings V.2

DOI

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neelam zia: This protocol has been developed to support a rigorous, ethical, and person-centred evaluation of adapted behaviour change techniques (BCTs) for adults with learning disabilities across healthcare and social care services within the same organisation. The study reflects a commitment to improving the quality, accessibility, and effectiveness of behavioural interventions for a population that experiences persistent health inequalities and barriers to engagement. The design of this protocol has been informed by clinical experience, service feedback, and the principles of the Mental Capacity Act (2005), ensuring that the rights, dignity, and preferences of adults with learning disabilities remain central throughout the research process. Particular attention has been given to accessible communication, supported decision-making, and the use of consultee processes where individuals may lack capacity to consent. A pre-study literature review will be conducted to ensure that the intervention design, outcome measures, and adaptation framework are grounded in the best available evidence. This review will also help identify gaps in current practice and research, strengthening the rationale for the comparative approach taken in this study. The protocol has been written to align with the expectations of IRAS, as well as the xyz research review process, due to it involving service users, and organisational R&D governance. It includes detailed procedures for consent, safeguarding, data protection, and mixed-methods analysis to ensure transparency and reproducibility. The study has been designed to minimise burden on participants and staff while maximising the practical value of the findings for frontline practice. This research is intended not only to generate evidence but also to contribute to a culture of reflective, compassionate, and evidence-based care. The insights gained will be shared with service users, carers, staff, and organisational leaders, with the aim of informing future training, service development, and policy. I would like to acknowledge the contributions of colleagues, service users, carers, and PPI partners who have shaped the development of this protocol. Their perspectives have been invaluable in ensuring that the study is grounded in real-world needs and priorities.



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We use this protocol and it's working

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Abstract

Adults with learning disabilities (LD) experience significant health inequalities and often receive support across both healthcare and social care services. Behaviour Change Techniques (BCTs) are widely used to support health and wellbeing, yet there is limited evidence on how these techniques should be adapted for adults with LD, and whether their effectiveness differs across service contexts. This mixed-methods study aims to evaluate the implementation, acceptability, and outcomes of adapted BCTs delivered within healthcare and social care services of the same organisation.

Before data collection, a systematic literature review will be conducted to identify existing adapted BCTs, adaptation frameworks, and outcome measures. Findings will inform the intervention design, adaptation strategies, and measurement tools used in the study.

The research comprises two parallel arms: (1) adapted BCTs delivered in healthcare services, and (2) adapted BCTs delivered in social care settings. Quantitative data will be collected at baseline, post-intervention, and follow-up to assess changes in target behaviours, engagement, quality of life, and staff confidence. Qualitative interviews and focus groups with adults with LD, carers, and staff will explore experiences of the intervention, accessibility, and contextual influences on implementation. A convergent mixed-methods approach will integrate findings to identify similarities and differences between settings.

Participants will include adults with LD who are receiving support from the organisation's services. Consent processes will follow the Mental Capacity Act 2005, using accessible information, supported decision-making, and consultee involvement where individuals lack capacity. Ethical considerations include safeguarding, minimising distress, and ensuring confidentiality and data protection.

The study requires to go through IRAS, as well as the Cygnet research review process, due to it involving service users) and approval, and organisational R&D governance approval. Where social care services fall under local authority or regulated provision, local social care research governance processes will also be followed. Findings will inform evidence-based, person-centred practice and provide practical recommendations for implementing adapted BCTs across health and social care services, with the aim of improving outcomes and reducing inequalities for adults with learning disabilities.



Guidelines

Core BCTs (refined by the literature review and PPI) may include:

- **Goal setting** (behaviour/outcome)
- **Action planning****
- **Prompting/cues****
- **Feedback on behaviour****
- **Reinforcement/reward****
- **Problem solving****
- **Social support****
- **Environmental restructuring****

Adaptations for adults with learning disabilities will be guided by:

- Literature review findings
- Organisational policies on accessible communication and reasonable adjustments
- Co-design with service users and carers

Materials

- Participant information sheet
- Debrief
- Consent form
- Interview schedule, surveys, questionnaires etc



Safety warnings

- ❗ ****Potential risks:****
- Emotional discomfort when discussing difficulties or behaviour.
 - Frustration if materials are not sufficiently adapted.
- **Mitigation:****
- Option for sessions with or alongside familiar staff.
 - Clear right to pause or stop at any time.
 - Distress protocol (stop, offer break, inform key staff, consider withdrawal).
 - Safeguarding procedures followed in line with organisational and statutory guidance.

Ethics statement

Research will comply with:

- **Mental Capacity Act 2005 (MCA)** for adults who may lack capacity.
- Data protection legislation and organisational information governance.
- Relevant professional and organisational ethical standards.

****Capacity and consent:****

- **Presumption of capacity:** Every adult is assumed to have capacity unless there is evidence otherwise.

- Support to decide:**

- Information provided in accessible formats (easy-read, visual aids, verbal explanation).
- Time and support from familiar staff/carers to aid understanding.

- Capacity assessment (research-specific):**

- Conducted by a trained member of the research team or appropriately trained clinician.
- Assesses ability to:
 - Understand relevant information
 - Retain it long enough to decide
 - Use or weigh it
 - Communicate a decision in any way.

- If capacity is present:**

- Obtain informed consent using accessible information sheets and consent forms.
- Emphasise voluntary participation and right to withdraw without impact on care.

- If capacity is lacking:**

- The MCA permits certain research involving adults lacking capacity with safeguards.
- A personal consultee (family member/close friend) will be asked whether the person would likely have wanted to take part.
 - If no personal consultee is available, a nominated consultee (independent from the research but familiar with the person's situation) may be approached, in line with organisational policy.
- The consultee advises on likely wishes; they do not give legal consent.
- The person's assent/dissent will be monitored; any indication of distress or objection will lead to withdrawal.

Outcome measures and data collection

- 1 Service user outcomes:
Quality of life (LD-appropriate measure)
Engagement/participation in sessions
Self-reported confidence or self-efficacy (adapted tools)
Staff outcomes:
Confidence in using BCTs
Perceived feasibility and burden
Process outcomes:
Fidelity to BCTs (checklists, session records)
Adaptation tracking (what was adapted, why, and for whom)
- 2 Data collection methods
Quantitative:
Standardised measures (where accessible)
Behavioural observation/ABC charts (if relevant)
Routine service data (e.g., incident reports, attendance)
Qualitative:
Semi-structured interviews with accessible formats (visual prompts, simplified questions, 1:1 or small groups)
Carer and staff interviews/focus groups
Field notes on context and implementation.

Data analysis

- 3 Quantitative analysis
Descriptive statistics for participant characteristics and baseline measures.
Within-group change (pre-post) in each setting using appropriate tests (e.g., paired t-tests, non-parametric equivalents, or mixed models).
Between-setting comparisons (health vs social care) using regression models adjusting for key covariates (e.g., level of LD, communication needs, co-morbidities).
Exploratory subgroup analyses (e.g., by level of support needs) if numbers allow.
- 4 Qualitative analysis
Thematic or framework analysis of interview/focus group data.
Coding will attend to:
Perceived accessibility and helpfulness of BCTs
Differences in experience between health and social care
Organisational and relational facilitators/barriers.
- 5 Mixed-methods integration
Convergent design:

Quantitative and qualitative data analysed separately, then integrated.
Joint displays or narrative integration to link “what changed” with “how and why”.
Particular focus on explaining any differences between healthcare and social care settings.

Ethical considerations, consent, and approvals

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The consultee advises on likely wishes; they do not give legal consent.
The person’s assent/dissent will be monitored; any indication of distress or objection will lead to withdrawal.
- 7 Consent documentation
For adults with LD:
Easy-read participant information sheets (PIS)
Accessible consent forms (symbols, large print, clear layout)
For carers and staff:
Standard PIS and consent forms.
For consultees:
Personal/nominated consultee information sheets
Consultee declaration forms.

Ongoing consent:

Consent treated as a process; willingness checked at each contact.

8 Risk, distress, and safeguarding

Potential risks:

Emotional discomfort when discussing difficulties or behaviour.

Frustration if materials are not sufficiently adapted.

Mitigation:

Option for sessions with or alongside familiar staff.

Clear right to pause or stop at any time.

Distress protocol (stop, offer break, inform key staff, consider withdrawal).

Safeguarding procedures followed in line with organisational and statutory guidance.

9 Legal and ethical framework

Research will comply with:

**Mental Capacity Act 2005 (MCA) for adults who may lack capacity.

Data protection legislation and organisational information governance.

Relevant professional and organisational ethical standards.

10 Confidentiality and data protection

Data pseudonymised and stored securely according to organisational policies.

Access restricted to authorised research team members.

Reporting in aggregate/anonymised form; no individual identifiable.

11 Required ethics and governance approvals

The study requires to go through IRAS, as well as the Cygnet research review process, due to it involving service users) and approval.

Organisation-level research governance:

Approval from the organisation's R26D/research office, covering both health and social care arms.

If social care is under local authority or independent provider:

Local social care research governance processes.

Where applicable, consideration of Social Care REC (or equivalent) if not covered by NHS REC.

Regulated services (e.g., CQC-regulated):

Ensure alignment with regulatory expectations on consent, capacity, and safeguarding.

In practice, for a single organisation delivering both health and social care:

Use a single, unified protocol and apply for:

NHS REC + HRA approval (if any NHS involvement), plus

Organisational R26D approval that explicitly covers social care sites.

Public and patient involvement (PPI)

12 Involve adults with LD, carers, and frontline staff in:

Refining research questions and outcomes.



Co-designing adapted materials (PIS, consent forms, visual tools).
Advising on recruitment, data collection, and interpretation.
Provide accessible feedback on study progress and findings (easy-read summaries, group feedback sessions).

Recruitment and sampling strategy

- 13 Identification: Clinicians and social care staff identify potentially eligible participants from caseloads.
Initial approach:
Staff introduce the study using brief, accessible information.
With permission, researchers meet the person (and carers) to provide full information and assess capacity.
Sampling:
Aim for diversity in:
Level of learning disability
Communication needs
Living situation (supported living vs residential)
Type of target behaviour (health vs social/functional).

Timeline

- 14 Months 1–3: Literature review; PPI workshops; finalise protocol and measures.
Months 4–6: Ethics and governance approvals; develop materials; staff training on BCTs and research procedures.
Months 7–18: Recruitment and data collection (quantitative and qualitative).
Months 19–22: Data analysis and mixed-methods integration.
Months 23–24: Write-up, dissemination, and implementation planning.

Dissemination and implementation

- 15 Internal:
Presentations to organisational leadership and teams.
Accessible summaries for service users and carers.
External:
Conference presentations, peer-reviewed publications, practice briefings.
Implementation:
Translate findings into practical guidance, training modules, and tools for adapted BCTs across health and social care services.

Acknowledgements

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