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FULL TITLE OF THE STUDY

Establishing the path to a large scale RCT of Positive Behavioural and Active Support (PBAS): a digital technology for supported living services in learning disability

SHORT STUDY TITLE / ACRONYM: PBAS Evaluation Pathfinder

PROTOCOL VERSION NUMBER AND DATE: v.1 30.01.2024

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: .... Date: ....../....../......

Name (please print):

....

Position:

....

Chief Investigator:

Signature: .... Date: ....../....../......

Name: (please print):

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LIST of CONTENTS

KEY STUDY CONTACTS

Chief Investigator	Prof Alexander Toogood
Joint Lead	Prof Vaso Totsika
Key Protocol Contributors	Prof Vaso Totsika: v.totsika@ucl.ac.uk Prof Alexander Toogood: s.toogood@pbas.app Dr Rachel McNamara McNamara@cardiff.ac.uk Dr Rebecca Playle playlera@cardiff.ac.uk Prof Manuel Gomes m.gomes@ucl.ac.uk
Committees	Advisory Group

STUDY SUMMARY

Study Title	Establishing the path to a large scale RCT of Positive Behavioural and Active Support (PBAS): a digital technology for supported living services in learning disability.
Internal ref. no. (or short title)	PBAS evaluation
Study Design	Mixed methods feasibility study
Study Participants	Providers of supported living services to adults with a learning disability (LD); LD service commissioners; adults with LD in supported living services; support staff in supported living services
Planned Size of Sample (if applicable)	Approx N=40 service providers Approx N=10 service commissioners N=15-20 approx. adults with LD and staff in supported living services
Planned Study Period	January 2024- December 2024
Research Question/Aim(s)	The aim is to investigate the feasibility of undertaking a randomised controlled trial evaluation of a digital technology called PBAS (Positive Behaviour and Active Support) in supported living services for people with learning disabilities

KEY WORDS: Learning disability, supported living services; residential services; learning disability service commissioning; adults with learning disabilities

STUDY PROTOCOL

Establishing the path to a large scale RCT of Positive Behavioural and Active Support (PBAS): a digital technology for supported living services in learning disability.

1 BACKGROUND

About 2.6% of the adult population in the UK have a learning disability (LD) (Hatton et al., 2016); this is 930,400 adults in England, of whom 129,000 receive social care support. Approximately 15,000 people with LD are known to services in Wales. Residential care and supported living represent the two highest costs in social care spend for adults with LD: £1.7 billion, and £933 million, respective annually. Local Authority (LA) social care spending for adults with LD represents 39% of total spend, and it is the second highest cost, after older people's services (NAO, 2017). Despite high costs, the quality of care is variable. One of the major challenges has been the adoption of care practices that promote good quality of life (QoL) for people with LD. Activity engagement is one of the core indicators of QoL in LD. In the early phase of deinstitutionalisation, data suggested wide variation in activity engagement (between 8% and 74% of time; Hatton & Emerson, 1996). These figures failed to improve as residential care developed. Recent data indicate that adults with LD spend less than 50% of their day in meaningful activity (Qian et al., 2015). A similar picture is evident for other aspects of QoL: low levels of community participation, low levels of choice and independence, and poorer well-being (Grey et al., 2018, Stancliffe et al., 2011; Verdonschot et al., 2012). Repeated exposure of abuse in LD services (Winterbourne view, Whorton Hall, and Hesley) highlights that services still fail to adopt service models that promote activity engagement and a good QoL for people with LD.

The proposed programme aims to build the evidence base for a digital technology called PBAS (Positive Behaviour and Active Support). PBAS is the digital translation of an evidence-based model of care called Active Support. Active Support (AS) is a care model that promotes QoL by increasing activity engagement with appropriate support from staff. AS promotes social interaction, skill acquisition, and community involvement, while also reducing the risk of challenging behaviour. The core principle in AS is that people with LD have the right to live a socially valued life like any other person, including being treated as an individual, having access to activities, being part of the community and having good relationships with others (Jones et al., 2009). The premise of AS is that every person with LD should engage in activities in and out of their house throughout the day with support from staff. For this, staff need to support people to engage in activities (active support), rather than do activities for them (hotel model of care). Staff behaviour change is thus the main mechanism of change in AS.

It has been shown that AS leads to increased levels of engagement in social and non-social activities in and out of the house and improved quality of staff support (Flynn et al., 2018; Toogood et al., 2016; Totsika et al., 2008). Increased activity levels are associated with improved QoL(Simoes & Santos, 2016), lower levels of challenging behaviour (Bowring et al., 2017), depression (Jahoda et al., 2017), and, in the longer term, may also contribute to the development of adaptive skills (Mansell et al., 2002). AS is a fully manualised intervention (Jones et al., 2002, Toogood 2010). To implement AS, staff need to be trained in a group workshop (1-2 days), then have a 1:1 tutorial in their place of work. Implementation is supported by several paper-based systems: Activity and Support Plans (daily diaries for mapping each resident's activities and staff support), participation records (a system for tracking activity engagement for each resident), task analysis for key activities (a step-by-step guide for activities the person needs support doing); Opportunity plans and teaching plans (descriptions of activities the person is currently learning).

Despite the evidence base for its effectiveness, AS has had limited uptake in UK services and limited success moving to different countries (Qian et al., 2019). Problems sustaining implementation are the main reason for its limited uptake. As part of Totsika's NIHR SSCR fellowship on AS, we conducted extensive PPI consultations with service providers and staff who indicated that: AS relies on outdated paper and pen technologies; the existing manuals are not comprehensive or easy to access; the training approach over-relies on expensive and scarce external trainers, and staff training is incompatible with services' current financial operational models (it is no longer viable to send an entire team out for training); training includes no support for implementation beyond the initial workshop and Interactive Training model, and no mechanism to mitigate against staff turnover (which results in services trying to implement AS with untrained staff). Further PPI consultations indicated that, despite implementation issues, residents with LD really value activity engagement, especially community activities, and the experience of positive social interactions. Staff value and want training on how to support service users to engage in activities. Altogether, PPI consultation findings provided strong support for further development of AS but identified a significant mismatch between a model developed by experts 30 years ago, and the realities of service provision in the 21st century.

2 RATIONALE

PBAS- the digital technology

In direct response to those findings, an independent provider organisation (Special Needs Care: SNC) developed a tablet-based app (PBAS) to translate Active Support into a digital tool. PBAS includes both training and implementation material for AS. A service that starts to use PBAS needs training in how to prepare the app and how to use it. They then need to start using the app to guide and document daily implementation. Like AS, PBAS is a multi-feature product that includes skills teaching, behavioural assessment, online reporting, and e-learning, in addition to the daily activity and support plans. The app runs on all devices and operating systems when an internet connection is available. One device is needed per setting for up to five people. Once enabled, service users and staff access the app several times a day using touch controls. Features such as activity planning and skills teaching are activated from the dashboard. Pre-populated activities appear in a person's calendar view. Spaces between activities are filled with activities selected from home and community. Scripts and customs are viewed when more detail is needed, and staff update digital participation records via the screen. Learning goals are set weekly, taught, and monitored daily.

Features added following testing and feedback from users include medication administration management and visual multi-media feedback. A minimum viable product (MVP), built on the concept of supporting personal routines, was field-tested, and evaluated in 8 supported living services (Toogood et al., 2020). Activity engagement and community involvement increased following intervention, suggesting that the mechanism of change of the digital PBAS is the same as that of AS (Toogood et al., 2020). It remains to be demonstrated whether PBAS adoption leads to effective change for services and people with LD. PBAS is currently used in SNC and is gradually being taken up by several other LD service providers.

Before an effectiveness and cost-effectiveness evaluation of PBAS can be undertaken, a number of key uncertainties need to be addressed, and are the focus of the proposed feasibility study. One of these is the willingness of services to adopt the PBAS app as part of their regular service provision and their willingness to participate in a future RCT. Currently, service providers have a range of apps that they use for some areas of functioning: e.g., apps to monitor medication use, methods (electronic or paper) to monitor challenging behaviour incidents. Services do not typically keep track of what activities people do on an hourly basis and what staff support is available, though electronic systems of staff allocation on a shift basis are available everywhere. Equally, services have access to some service data, but they do not have access to continuous real-time data. Services may be reluctant to adopt a new app that captures some of the information for which they already have systems. Services may be reluctant to invest in training to use a new app if they have already invested in other apps. Therefore, the first step in designing a large-scale RCT is to investigate the willingness of services to adopt the PBAS app for their service users.

Additional objectives of the present study are to (a) work alongside service users with LD and staff to determine what is the most acceptable way to capture the primary outcome in a future RCT (engagement in activities of daily living typically measured via real-time observation by independent researchers), their views on how much change in activity engagement they would like to see and what is the most efficient/acceptable outcome package for measuring secondary outcomes in a future RCT – see logic model for anticipated outcomes; (b) to determine the comparator for a future RCT by providing a comprehensive description of current practice in relation to systems/apps used in LD service providers (i.e., Treatment as Usual-TAU), and how services plan and monitor opportunities for activity and social engagement, skills teaching, and behaviour change, and (c) to design a comprehensive health economics evaluation for the RCT, including an assessment of the most appropriate generic health-related QoL outcome measure for evaluating cost-effectiveness for this population (for example, validated generic QoL measures such as the EQ-5D are not available for people with LD (Russell et al., 2018)).

Objectives

(1) To determine the feasibility of recruiting service providers in a future large-scale RCT by investigating their willingness to adopt the PBAS app as part of their regular service provision and their willingness to be randomised in a trial of the intervention.
(2) To co-produce an evaluation package that is acceptable to staff and service users;
(3) To provide a comprehensive description of TAU
(4) To design a comprehensive and bespoke economic evaluation for the RCT;

3 THEORETICAL FRAMEWORK

The theoretical framework underlying the Active Support intervention and subsequently the PBAS app is the theory of normalisation and in particular the right to be supported to create and maintain a valued lifestyle expressed in terms of the moment-to-moment lived experience of daily life (Totsika et al., 2008). The philosophy of active participation is combined with the science of applied behaviour analysis to underpin Active Support/PBAS so as to provide the means through which adults with a learning disability can be supported to participate fully in their own lives.

The theory of change associated with the adoption of PBAS within support living/residential services for people with a learning disability is outlined in the logic model – please see in Appendix.

4 RESEARCH QUESTION/AIM(S)

Aim: The aim is to investigate the feasibility of undertaking a randomised controlled trial (RCT) evaluation of a digital technology called PBAS (Positive Behaviour and Active Support) in supported living services for people with learning disabilities.

4.1 Objectives

(1) To determine the feasibility of recruiting service providers in a future large-scale RCT by investigating their willingness to adopt the PBAS app as part of their regular service provision and their willingness to be randomised in a trial of the intervention.
(2) To co-produce an evaluation package that is acceptable to staff and service users;
(3) To provide a comprehensive description of TAU
(4) To design a comprehensive and bespoke economic evaluation for the RCT.

4.2 Outcome

The outcome of this study will be the protocol for a definitive RCT of PBAS in supported living services for people with LD.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

<u>METHODS</u>

To address Objective 1 (O1), we will conduct a survey of LD service providers (N=30) and individual interviews with LD service providers (N=10). In the survey, questions will ask participants about their willingness to (a) adopt PBAS for use in their service and (b) their willingness to participate in a future RCT of the app. These questions will be measured on a 5-point scale from very willing to not willing at all. The survey will also include free-text questions exploring the barriers and facilitators for (a) adopting PBAS in services and (b) participating in a RCT.

Qualitative interviews will include questions on willingness to adopt PBAS for service use and willingness to participate in a future RCT evaluation of PBAS, as well as questions about the barriers and facilitators of service adoption and RCT participation. Qualitative interviews will also include questions on the pathways typically followed in service provider organisations to determine software purchases/implementation and research participation.

Qualitative interviews will follow a semi-structured schedule and questions will be open ended. Service providers who participate in the survey will only be invited to participate in the survey through a wide reaching invitation (see recruitment). Service providers invited to be interviewed will be purposefully selected and invited to interview because of their role in service provider organisations (able to make decisions regarding research participation or technology adoption). There may be partial overlap in the respondents to the interview vs those interviewed, though because of anonymous participation we will not be measuring this. The different approaches to recruitment might prevent extensive overlap in the two groups. Qualitative interviews aim to capture more in-depth information about barriers and facilitators to technology adoption and RCT participation, as well as provide a description of pathways to decision making in service providers.

To address O2, we will interview approximately 10 adults with a learning disability, we will run 3 focus groups with adults with a learning disability and support staff (approx 15-20 people in total for the focus groups), and we will interview approximately 10 learning disability service commissioners. During the focus groups, we will discuss participants' views on (a) the potential outcome areas that should be measured in a PBAS RCT evaluation, (b) the acceptability of direct observation as a measure to be used in a PBAS RCT (to evaluate the primary outcome of activity participation for residents) and views on potential alternatives and (c) views on how much daily activity participation people think is needed to make a real difference to the lives of residents in supported living services. The 1:1 interviews with adults with a learning disability will focus on what outcome areas should be measured in a PBAS RCT evaluation. Interviews will be used where participants experience significant communication difficulties and need additional support to express their views. Questions (for the focus groups and interviews) will be open-ended and will be supported by easy read material and/or Talking Mats – a technology that facilitates 1:1 interviewing adults with ID.

The interviews with the LD commissioners will include questions on the alignment between PBAS outcomes and service outcomes as well as prioritising PBAS outcomes that align with LD service outcomes from the perspective of commissioning.

A literature review will also be used as a method to identify measures suitable to measure PBAS outcomes.

To address O3, we will draw on data collected from the LD service provider survey. For this, the survey will include questions on what apps or software and paper-based systems are currently being used by services to capture information in relation to (a) service user activity and staff allocation; (b) medication use; (c) challenging behaviour and monitoring of interventions related to challenging behaviour; (d) skill development goals and monitoring of interventions for skill development (for service users); (e) other quality of life outcomes for service users (e.g., community participation). For each of these questions, when a participant indicates an app or software is used, we will also ask about (a) cost of the technology (if known); (b) ease of use of each technology and (c) perceived extent of implementation. The survey will provide free-text space for any other comments participants may have on apps/software or paper-based systems used in services.

To address O4, we will do a literature review to identify all generic health-related QoL measures used in RCTs for disabled populations and their suitability for use with adults with a learning disability. Information from the focus group (question a of focus groups) and interviews with adults with a learning disability will be used to weigh the final measure selected. Costs on PBAS and other technologies used in services will be collected by the service provider survey (see above) and own knowledge.

DATA ANALYSIS

RO1: Willingness to adopt PBAS and participate in future RCT: Analysis of quantitative data from the LD survey in addition to qualitative data from interviews with service providers to assess likelihood of these two parameters. For the quantitative data on willingness we will use descriptive statistics (frequencies and percentages).

A framework analysis will further identify barriers for PBAS adoption and barriers for research participation: using an existing definition of barriers and facilitators we will code the data using a bottom-up approach to identify barriers and facilitators for both app adoption and RCT participation. We will undertake a framework analysis on free-text data from the survey and qualitative data from the interviews and we will combine the findings.

Qualitative data on pathways for decision making regarding technology adoption and research participation will be synthesised.

RO2a. Acceptability of proposed primary outcome measure: A thematic analysis (bottom-up) of data from focus groups with service users and staff will investigate the acceptability of the proposed method for capturing the primary outcome in a large RCT (the primary outcome is activity engagement typically measured by structured, real-time observations undertaken by a researcher who is present in the residential setting and does not interact with anyone but follows people around (except for bathrooms and bedrooms) to observe level of engagement and support from staff). A thematic analysis will identify any alternative methods mentioned by participants and the acceptability of this approach of alternative approaches.

To estimate Minimally Clinically Important Difference (MCID) in relation to the primary outcome (activity engagement), we will draw on the existing systematic review (Flynn et al., 2018), expert co-investigator views and data from service users and staff views (focus groups) on the amount of change in daily activity engagement that they consider makes a real difference to their lives.

RO2b. Acceptability of outcome package: the logic model of Active Support (see Appendix) identifies a number of areas impacted by the introduction of Active Support. Each of these areas can be assessed during a RCT, though the time and resource demand placed on participants is significant.

A thematic analysis of focus group and interview data will identify what outcomes participants consider the most important. A thematic analysis of data from interviews with service commissioners will identify outcome areas that align with guidance for commissioning decisions. Findings from these two analyses will be discussed at the PMG and a consensus will be reached on what outcome areas will be evaluated in a future RCT. We will draw on the findings of the literature review plus team expertise to map outcome areas to measures.

RO3. Comprehensive description of current practice (Treatment as Usual; TAU): Descriptive statistics will be used to analyse quantitative from the service provider survey to identify what apps or software and paper-based systems are currently being used by services to capture information in relation to (a) service user activity and staff allocation; (b) medication use; (c) challenging behaviour and monitoring of intervention related to challenging behaviour; (d) skill development goals and monitoring of interventions for skill development (for service users); (e) other quality of life outcomes for service users (e.g., community participation). Descriptive statistics will be used to quantify information on (a) ease of use of each technology and (b) perceived extent of implementation.

RO4. Design a comprehensive health economics evaluation package: A list of generic health-related QoL measures used in RCTs with disabled populations will be generated by the literature review. The literature review will also generate information on the suitability of each measure for use with adults with ID. A thematic analysis of focus group data will explore what is the most acceptable area of health where change is expected to be seen (e.g., overall health, overall QoL, physical health, mental health). Descriptive statistics of cost data from the survey will determine the feasibility of costing TAU in the RCT.

6 STUDY SETTING

Survey: online/remotely.

Interviews: Mostly remotely via Microsoft Teams. Where requested, interviews may take place in the location where the participant works or lives (if a residential house/supported living accommodation) or a location that is happy to host the interview (the office of a service provider, SNC premises).

Focus groups: these will take place face to face in premises provided by service providers or organisations associated with co-applicants from services (e.g., SNC, Drive).

7 SAMPLE AND RECRUITMENT

7.1 Sampling

To be eligible to participate in surveys and interviews for this project, participants need to have experience of supported living or residential services for people with LD: this could be from the perspective of a provider, commissioner, staff or service recipient.

Service recipients are people with moderate or severe LD who are in single-person or small group (1-5) staff supported living accommodation. Staff are persons employed to work in supported living services as: direct carers, practice leaders, managers, or supervisors.

To be included in the surveys and interviews, participants may be

- Adults (over 18 years old) with moderate or severe learning disabilities in supported living services in England and Wales.
- Staff related to supported living or residential services for adults with a learning disability: staff roles relate to purchase of supported living services (commissioning), management of supported living services, and provision of direct support. Supported living services organisations may be based in England or Wales.

Settings and individuals excluded are day service and colleges, treatment units and hospitals, and individuals with learning disabilities living at home with family or in shared lives schemes. Also excluded are CQC-registered services providing nursing support (as opposed to residential or supported living support).

Convenience sampling will be used throughout except for service provider interviews where purposive sampling will select service providers to be invited for an interview depending on their role within supported living organisations. Convenience sampling will be used for the service provider survey because random or representative selection is not possible – see below. We will consider geographical spread when recruiting- see below.

We have not undertaken a formal power analysis for this study as this is not consistent with the aims of this project.

There is no list of all LD service providers in the UK and the total number of LD service providers is thus unknown. We will compile a list of care providers from local authorities' pages (each local authority should list providers under its local offer) and we will cross-check their registration with CQC or CSIW (that they offer residential or supported living services to people with LD). We will aim to recruit at least one provider operating in each of the nine official regions in England and the four regions in Wales. Some very large providers operate throughout the country (e.g., Mencap, United Response). As the total number of providers is not known, we cannot estimate how representative the number of providers will be. Thus, we aim to recruit at least 30 providers, a number that allows for the estimation of descriptive statistics and we will keep on recruiting until we get close to this number (i.e., we will invite a larger number of people, estimating a response rate of about 30%).

Service providers identified through our list will be contacted to complete the survey. Once close to 30 responses have been collected and the geographical spread is satisfactory, the survey will close to recruitment. Service providers will be recruited for interviews through convenience sampling (either from survey recruitment or advertisement through co-investigator networks). Staff and people with LD will be recruited through local or national networks (e.g., Choice Forum). People with LD who have more limited verbal communication skills will be invited to participate in 1:1 interviews. Interviews will be facilitated via tools such as Talking Mats©, based on the experience and preference of the person with LD. All participation will be anonymous.

We will develop a list of LD service providers as described above and we will contact them about completing the survey using emails addresses found in providers' webpages. We will use social media as an additional means of advertising the survey.

We will use our networks to invite LD service providers, LD service commissioners, staff and adults with LD to participate to the survey, focus groups and interviews.

We will use our networks to identify LD service providers who might be willing to pass on information about the survey, focus groups and interviews to their staff and residents.

7.2 Consent

According to the UK GDPR (https://www.legislation.gov.uk/eur/2016/679), informed consent is required for the processing of personal data. As the none of the current project's data collection methods (survey to service providers, interviews with service providers, interviews with commissioners, focus group/interviews with staff in services and adults with a learning disability) will involve the collection of *any* personal information. no informed consent is required. Participation in the survey will be anonymous and no personal data will be required/collected. This similarly applies to the interviews with service providers and service commissioners. No informed consent is required for participation in focus groups and interviews for staff in services and adults with a learning disability. Of note, no personal information will be recorded about the interviews & focus groups (we will not record the name of the person being interviewed or the name of their service provider on the interview file, we will not record in the transcript whether the person talking has a learning disability/is a resident or staff).

Participants will still receive information about the activities they are participating (in the form of an information sheet).

8 ETHICAL AND REGULATORY CONSIDERATIONS

Below we review possible risks arising from contributing to this project and their management.

8.1 Assessment and management of risk

Consistent with our approach to fully anonymous participation in this project:

- No names of individuals will be noted as part of the survey or interviews.
- In the survey, we will collect grouped information to describe who is completing it: we will provide a group of roles for people to select, grouped year groups for number of years working in this role)

- The survey and provider interviews will not collect information on the names of organisations. Information regarding organisations will be collected in grouped form (grouped number of staff working in organisation to determine size of organisation, name of country (England, Wales, Scotland, NI) where organisation provides supported living services, name of region (9 regions in England and 4 in Wales) where organisation is based and operating). This applies to organisations offering supported living services and organisations employing commissioners to be interviewed.

- Focus group transcripts will not link a person's status with the information they provide, i.e., we will not transcribe information on views and then link it to a person identified as staff vs service user. No names or pseudonyms will be used in transcripts to identify *who* speaks (speakers will be denoted by a letter e.g., P). If names are mentioned by participants *during t*he context of an interview referring to someone else, these will be omitted from the transcript and generic descriptors will be used in their place ('staff', service user', 'manager').

- Interviews transcripts (following interviews with adults with LD) will not include the name of the person or the name of the organisation that provides them with supported living services, either in the body of the transcript or the file name. If names are mentioned by participants *during t*he context of an interview, these will be omitted from the transcript and generic descriptors will be used in their place ('staff', service user').

- Where recordings are to be made for the purposes of transcription, these will be audio only and will not involve video.

  All this information will be provided to those who participate in the survey, interviews or focus groups in the form of an 'information sheet' preceding the data collection.

Informed Consent:

According to the UK GDPR (https://www.legislation.gov.uk/eur/2016/679), informed consent is required for the processing of personal data. As the current project will not collect *any* personal information, no informed consent is required.

Safeguarding vulnerable adults:

Service users with a learning disability will participate in the focus group and interviews supported by their support person. Researchers will undergo an enhanced DBS check and will not be interviewing participants with a learning disability on their own.

If, during the context of an interview or focus group, any participant mentions anything that raises safeguarding concerns, the researcher will raise it with the support person immediately requesting the concern is logged with the organization that supports the person with the learning disability. The researcher will also follow the safeguarding protocol and procedures of the sponsor (Special Needs Care Ltd). In the presence of a safeguarding issue, individual and organisation names will be noted when following the safeguarding protocol. The researchers will receive Safeguarding training at the start of their employment with SNC Ltd and will also be trained on any other mandatory training SNC requires according to their training policy.

Safety of the researcher

Most data collection will take place remotely. Where interviews are conducted face to face, these will include a support person present (for interviewees with a learning disability) and/ or take place during working hours in a public space. Focus groups will include a second researcher. SNC includes a lone worker policy which will be followed.

Data security:

All information collected as part of this project will be saved in a secure and access-controlled part of the SNC server. Information will only be available to the investigators and researchers.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

According to the HRA decision making tool, the current project does not constitute research. However, as the current project involves adults with a learning disability, we sought the opinion of the Research Ethics Committee (REC) of the School of Medicine, Cardiff University. The REC indicated that they consider the proposed piece of work extended Patient and Public Involvement (PPI) consultations to support the development of the protocol of a future study and as such, they do not need to review the protocol.

8.3 Access to the final study dataset

All people named as contributors to the protocol will have access to the data arising from the study. All data are anonymous and will be shared via secure channels (e.g., Teams, FastFile). The named protocol contributors require access to the data because they are leading workgroups that require the data to feed into the work required to be added to the RCT protocol. Researchers will also have access to the data for the period of their contract with SNC.

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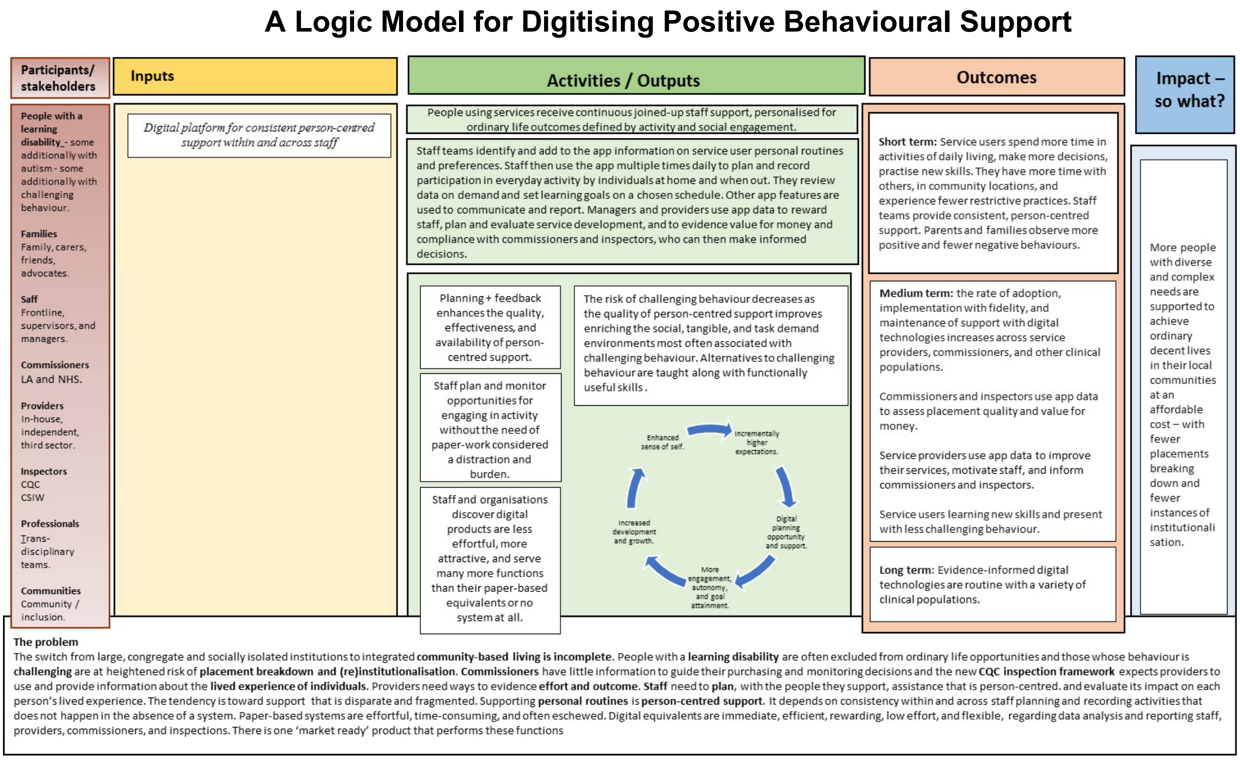
11. APPENDICES

Appendix 1: PBAS Logic Model



A Logic Model for Digitising Positive Behavioural Support

Participants/ stakeholders

People with a learning disability_- some additionally with autism - some additionally with challenging behaviour.

Families
Family, carers, friends, advocates.

Saff
Frontline, supervisors, and managers.

Commissioners
LA and NHS.

Providers
In-house, independent, third sector.

Inspectors
CQC
CSIW

Professionals
Trans-disciplinary teams.

Communities
Community / inclusion.

Inputs

Digital platform for consistent person-centred support within and across staff

Activities / Outputs

People using services receive continuous joined-up staff support, personalised for ordinary life outcomes defined by activity and social engagement.

Staff teams identify and add to the app information on service user personal routines and preferences. Staff then use the app multiple times daily to plan and record participation in everyday activity by individuals at home and when out. They review data on demand and set learning goals on a chosen schedule. Other app features are used to communicate and report. Managers and providers use app data to reward staff, plan and evaluate service development, and to evidence value for money and compliance with commissioners and inspectors, who can then make informed decisions.

Planning + feedback enhances the quality, effectiveness, and availability of person-centred support.

Staff plan and monitor opportunities for engaging in activity without the need of paper-work considered a distraction and burden.

Staff and organisations discover digital products are less effortful, more attractive, and serve many more functions than their paper-based equivalents or no system at all.

The risk of challenging behaviour decreases as the quality of person-centred support improves enriching the social, tangible, and task demand environments most often associated with challenging behaviour. Alternatives to challenging behaviour are taught along with functionally useful skills .

Outcomes

Short term: Service users spend more time in activities of daily living, make more decisions, practise new skills. They have more time with others, in community locations, and experience fewer restrictive practices. Staff teams provide consistent, person-centred support. Parents and families observe more positive and fewer negative behaviours.

Medium term: the rate of adoption, implementation with fidelity, and maintenance of support with digital technologies increases across service providers, commissioners, and other clinical populations.

Commissioners and inspectors use app data to assess placement quality and value for money.

Service providers use app data to improve their services, motivate staff, and inform commissioners and inspectors.

Service users learning new skills and present with less challenging behaviour.

Long term: Evidence-informed digital technologies are routine with a variety of clinical populations.

Impact – so what?

More people with diverse and complex needs are supported to achieve ordinary decent lives in their local communities at an affordable cost – with fewer placements breaking down and fewer instances of institutionalisation.

The problem
The switch from large, congregate and socially isolated institutions to integrated **community-based living is incomplete**. People with a **learning disability** are often excluded from ordinary life opportunities and those whose behaviour is **challenging** are at heightened risk of **placement breakdown and (re)institutionalisation. Commissioners** have little information to guide their purchasing and monitoring decisions and the new **CQC inspection framework** expects providers to use and provide information about the **lived experience of individuals.** Providers need ways to evidence **effort and outcome. Staff** need to **plan,** with the people they support, assistance that is person-centred. and evaluate its impact on each person's lived experience. The tendency is toward support that is disparate and fragmented. Supporting **personal routines** is **person-centred support.** It depends on consistency within and across staff planning and recording activities that does not happen in the absence of a system. Paper-based systems are effortful, time-consuming, and often eschewed. Digital equivalents are immediate, efficient, rewarding, low effort, and flexible, regarding data analysis and reporting staff, providers, commissioners, and inspections. There is one 'market ready' product that performs these functions

11.2 Appendix 2 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
	Version 1	01/02/24		