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Brain in Hand Research Report:

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NHS Foundation Trust

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Research Report

Psychological and quality of life impact of Brain in Hand - A mixed methods study

Department of Intellectual Disability Neuropsychiatry, Research and Innovation Team, Cornwall Partnership NHS Foundation Trust

IRAS Number: **297441**

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Summary

Brain in Hand is a digital self-management support system for adults who need help remembering things, making decisions, planning, or managing anxiety. It is particularly advocated to support people who having wellbeing needs emerge from autism spectrum disorder (ASD) or suspected of it.

This prospective mixed methods cohort study aimed to determine the impact of Brain in Hand, on the quality of life and psychological wellbeing of adults with an actual or suspected diagnosis of Level one ASD. The study was designed and conducted in real life routine practice conditions. Data were collected using validated anxiety (HADS) and clinician reported outcome HoNoS (LD) measures at baseline and after 12 weeks of using Brain in Hand.

Follow up data were collected on 66 of the 100 people recruited to the study. Just over a third of the initial cohort failed to complete. Statistically significant improvements were detected for anxiety and quality of life, with an overall effect size of 0.65. Specific positive changes were detected across five of the seven quality of life domains. The qualitative study (N=10) detected increases in confidence, independence, and self-management, and found that all participants would recommend the tool to others. Recommendations for improvements to the tool included enhanced mood tracking and more personalised onboarding.

The study is limited by the lack of a control group, but this is partially mitigated by data from a validation study of the HONOS LD measure. As a result of this study, Brain in Hand meets the minimum needed evidence of research effectiveness for Tier C of NICE Standard Evidence Framework for Health Digital Technologies.

Introduction

Autism Spectrum Disorder (ASD)

The prevalence of ASD in the United Kingdom (UK) is approximately 1.1%. [1] ASD is a lifelong pervasive developmental condition that affects the way that a person interacts with and experiences the world around them. [2] There has been an increase of 787% in recorded autism diagnoses between 1998 and 2018, and still believed that around 40% of autistic people remain undiagnosed. [3] It is suspected that there are a range of contributory factors for increased diagnosis, including evolving diagnostic systems, changes in reporting practices and self-awareness, especially in adults.[3]

ASD and mental health

ASD is associated with a higher prevalence of mental health problems. [4] In particular, day to day chronic anxiety is estimated in 40-50% of autistic people. [5] This is not un-expected as autistic people struggle to varying degrees in understanding changes in their environment, encounter communication and sensory difficulties and find emotional processing challenging. [6] Overall pooled data from a large meta-analysis in autistic clinical populations showed 20% (range:17-23%) for anxiety disorders, 11% (range: 9-13%) for depressive disorders and four percent (range: 3-5%) for psychosis spectrum. These mental illness rates are two to three-fold that of general population. Autistic adults are at significant risk of self-injurious behaviour with 66% contemplating suicide and 35% reporting a suicide attempt. [7, 8, 9] Preventative interventions are key to improving health outcomes for autistic adults. [10, 11, 12] However, there is a significant dearth of research into the impact of ASD in adulthood particularly on suitable and holistic interventions to help improve quality of life and reduce vulnerability to mental health concerns. [13] The pandemic has further exacerbated health inequalities, highlighting the need for innovative digital health interventions that reflect the current difficulties as a result of Covid-19. [14]

Economic impact of ASD

The UK healthcare workforce faces increasing demand to provide care for a growing autistic population. Costs are estimated to increase to £95bn by 2033. [15, 16, 17] The direct and indirect economic cost of failing to support autistic people in the United Kingdom (UK) was estimated to be £32bn in 2014, which continues to rise. [18, 19, 20, 21, 22]

Digital Health Tools

The five-year NHS autism research strategy for England has pledged a commitment to providing healthcare that is safe, effective, and tailored to meet individual needs with evidence-based research [23]. Technological innovations are increasing, creating a shift in NHS care, that can improve patient outcomes and significantly reduce costly recourses. [24] Limited research in this area of digital technology has led to missed opportunities to identify and implement effective products throughout UK healthcare systems. [25] Digital health tools offered an enormous potential for health care systems both during and after the pandemic with untapped potential to improve healthcare delivery and support a reduction in health inequalities. [14, 26, 27] While digital health tools can address the burgeoning need for quick and cost-effective interventions especially in life-long conditions such as ASD, questions still exist about user experience and evidence in general of effectiveness. There are a considerable number of ASD specific digital health tools available, however, the vast majority remain untested for effectiveness and useability. [28]

Brain in Hand

Website: https://braininhand.co.uk/

Brain in Hand (BiH) is a commercial digital health product, combining specialist human support with technology, to enable autistic people to live more independent lives. It has been designed in partnership with autistic people. BiH encourages individuals to build a person-centred individual support package with the opportunity for development of self-management skills. It aims to increase participation in education, employment, and community life. [29] BiH seeks to increase user confidence to cope with day-to-day stressors and where appropriate to reduce the reliance on statutory services or reliance on the user's support network.

Hypothesis

BiH will provide a person-centred experience to autistic individuals who satisfy or are suspected of a level one DSM5 autism diagnosis (Appendix 1) to increase self-reliance and improve mental wellbeing. [30]

Quantitative Aims

- To identify the impact of BiH on quality of life
- To examine the impact of BiH on mental health
- To estimate the level of acceptability of BiH (drop-out rates) and factors associated with drop-out

Qualitative Aims

- To discover how the traffic alert system and 24/7 support line impacted on the participants ability to manage events and internal experiences the person found difficult to manage or understand.
- To discover if BiH could improve a participant's ability to manage their day to day needs and improve their own awareness of their ASD experience.

Methods

Overview and Procedure

The research design was framed to test BiH against the 2019 Tier 3A (now Tier C) of the NICE Standard Evidence Framework for Health Digital Technologies which recommended a large cohort study to reference the strengths, weakness, and limitations. [31] The study followed a mixed methods prospective cohort design. Analyses and reporting followed STROBE guidance (32).

The Hospital Anxiety and Depression Scale (HADS) [33] was used to assess for presence and change of anxiety and depression symptoms. The Health of the Nations Outcome Scales for people with Learning Disabilities (HoNOS-LD) [34] was used as the measure of Quality of Life. The rationale for the selection of these two scales for the study is provided in Appendix 2. The two measures were then completed by telephone interviews at baseline and 3 month follow up, to establish changes in wellbeing and clinical symptomology after using BiH for a period of 12 weeks. Dropout rates in the study period were recorded. To ensure the mental state safety of participants, the screening process also involved application of the Columbia Suicide Severity Rating Scale to screen out anyone who might have suicidal ideation.

Ten percent of participants who completed baseline and subsequent follow up measures at 12 weeks, were randomly selected to take part in a semi-structured interview. Semi-structured interviews were designed to address the qualitative aims and gain insight into personal experience and usability of the BiH technology.

Sample size

A target sample size of 100 autistic people and those awaiting diagnostic confirmation, satisfying the inclusion and exclusion criteria was prespecified. Allowing for a 10% drop-out rate, this was chosen to provide 80% power at a significance level of 5% to detect a standardised effect size of 0.3 for the change in HADS from baseline to the 12-week follow-up. This represents a small effect size as defined by Cohen and was considered as the minimum clinically important difference (MCID).

Participants

Participants were recruited nationally across England and Wales from seven NHS sites through a combination of direct contact via telephone/letter and social media campaigns. This included Cornwall Partnership Foundation Trust, (Catchment Population 538,000), Devon Partnership Trust, (Catchment Population 890,000), Swansea Bay (Catchment Population 1.2M), Coventry and Warwickshire Partnership Trust (Catchment Population 1M), Hertfordshire Partnership Trust (Catchment Population 1.2M), Cheshire and Wirral Partnership Trust (Catchment Population 1M) and Haringey, Barnet and Enfield Mental Health NHS Trust (Catchment Population 1.2M) with a total catchment area of over 7M.

Inclusion Criteria

- All who have been diagnosed with ASD as per DSM-5 criteria level one or post screening by health professional knowledgeable of ASD such as a GP and on the confirmatory diagnostic pathway.
- Age ranges from 19 to 80.
- All have been screened by the Columbia Suicide Rating Scale (C-SSRS) as not having risk concerns of suicide or suicidal ideation.
- Access to smart devices with compatibility to running BiH.
- Has capacity to give informed consent and can give informed consent.
- Can understand the BiH information.

Exclusion Criteria

- Outside of stated age range within the inclusion criteria.
- Clinical intellectual disability
- Level 2/3 DSM V ASD.
- Diagnosed significant con-current psychological comorbidity (psychosis, severe depression etc.) that would limit the ability of the participant to take part in the study.
- Anyone who declines to give consent or are unable to give informed consent.
- Anyone who has been screened positive with the (C-SSRS) suicide risk scale.
- Not willing or able to engage with smart device/internet.
- Insufficient English language ability to understand and complete questionnaires.

Analysis

Associations between sociodemographic factors and whether participants had a confirmed diagnosis of ASD were assessed using Fisher's exact test. The overall effectiveness of BIH was assessed in pre–post analyses by comparing the mean outcomes in the cohort from baseline to three months using a paired t-test (presented with 95% CIs for the estimated change in outcomes). Multivariable linear regression models were used to determine whether changes in outcomes were associated with demographic factors, adjusting for baseline outcome scores. Four models were pre-specified to explore factors associated with changes in total HONOS-LD scores (joint primary outcome). The first model adjusted for regression to the mean by including baseline HONOS LD as a covariate. The second model compared HoNOS-LD scores in people receiving support to those not receiving support, after adjustment for baseline HoNOS LD and any significant sociodemographic factors (age, employment status, marital status). The third added measures of BiH engagement and the fourth the effect of a confirmed diagnosis of ASD. A similar structured approach was adopted for the multivariable analysis of the HADS Anxiety and Depression scales (joint primary outcomes). Univariable pre-post analysis was conducted to assess the effect of the intervention on each component of the HoNOS-LD (secondary outcomes). Due to non-normality of the component scores, the Wilcoxon Signed-Rank test was used to compare median HoNOS-LD component scores at baseline and three-month follow-up. A similar approach was taken to assessing change at follow-up for seven specific 'clusters' within the HoNOS-LD: behavioural problems, items 1-3; cognition, items 4 and 5; communication, items 6 and 7; mental state, items 8-11; physical problems, items 12 and 13; activities of daily living, items 14-16; social functioning, items 17 and 18. Bonferroni correction was conducted to account for multiple testing in the secondary analyses: for example, a more stringent p-value threshold of $p<0.003$ was used in place of the usual $p<0.05$ when assessing changes in individual HoNOS-LD component scores. Reasons for missing data were documented and the baseline characteristics of those with and without missing data compared. Logistic regression analysis was conducted to identify demographic and baseline characteristics associated with risk of drop-out. A normative analysis was conducted by comparing the reductions in total HoNOS-LD score in this study with changes seen in a previous validation study assessing reliability and sensitivity to change. [35]

Semi Structured interviews (appendix 3) were completed remotely at the 12 week follow up, transcribed and differences reconciled before conducting a thematic analysis following Braun and Clarke's six step process [37]. Both deductive and inductive approaches were used to generate themes, reflecting from both prior knowledge of the researchers and the development of themes that naturally emerged from the data. The process allowed in-depth conversations between the participant and researcher to gather perception, opinion, experience and emotion. [36,37] Thematic analysis drew from grounded theory and phenomenological approaches for considering and analysing data. [38] The qualitative semi-structured interview methodology helped gain an in-depth insight from participants on the study topic.

Ethics

Ethical approval for Psychological and quality of life impact of Brain in Hand - A mixed methods study was approved by the Health Research Authority (HRA) on 01/06/2021.

- REC: 21/SW/0066
- Protocol: CPT016
- IRAS: 297441

Results

A total of 103 people consented to the study. Post consent, two patients were excluded due to being ineligible, one participant was excluded, since the Columbian Suicide risk Tool screened positive for suicide risk. One participant was withdrawn post baseline data, since increased risk was observed by the regional principal investigator. In both cases all collected data i.e. baseline data was removed. Both participants excluded received support to reduce risk from their regional research team.

Of 101 fully recruited, two participants were lost due to concerns about COVID leaving a sample of 99 adults who either had a formal diagnosis of level one ASD (N=52) or confirmed to be of high suspicion of ASD and on the waiting list for confirmation of diagnosis (N=47). All those referred by the PIs for discussion and consideration to participate in the study consented.

Table 1 provides a summary of the socio-demographic factors of the participants (n=99). There were no noted statistical differences between the ASD diagnosed (n= 52) and those suspected of ASD (n=47) groups with regard to age dispersion, employment status, support received and accommodation (Table 1).

Quantitative analysis

Changes in HADS Scores

Of the 99 participants, 66 completed the HADS measure at follow up. A paired t-test showed a significant decrease in anxiety on the HADS between baseline and 12 week follow up after using BiH (Mean reduction = -2.23, 95% CI = -3.43 to -1.04, p= <0.001: Figures 1a and b). No change was observed for depression (Mean reduction = -0.59, 95% CI = -1.75 to 0.56, p = 0.31). There were no significant changes in the effect of BiH on anxiety or depression by sociodemographic factors or diagnosis of ASD.

Changes in total HONOS-LD Scores

Mean scores for the 99 participants completing the HONOS-LD at baseline were 18.7 (SD 7.6) (Table 2). Two HONOS-LD scores were missing due to COVID preventing the researcher team from conducting the interviews. Thirty-three people dropped out from the study. Three factors were associated with study drop-out rates. Findings show that participants in the 31-60 age bracket, and those in rented/other accommodation, were likely to be at higher risk of drop out, in comparison to those participants who were younger, or owned their own home. Findings also suggest that participants with high levels of anxiety were at less risk of drop out, than those with lower anxiety scores (Table 3).

Mean scores for 64 participants who repeated the HONOS-LD at follow up were 13.9 (SD 8.0). Further analysis of the data showed a statistically significant reduction in HONOS-LD total scores of 5.7 points (95% CI -7.8 to -3.5; p<0.001). Four models explored the principal factors which might be associated with any major variance in the HONOS-LD scores. Model one, adjusted by including baseline HONOS-LD as a co-variate to address regression to the mean, estimated the change from baseline to follow up as a

reduction in scores of 5.3. Model two showed an estimated mean reduction of 7.8 points for those not receiving support but a lower reduction of 1.5 points in those supported (p=0.006). No other sociodemographic factors were significantly associated with change in total HoNOS-LD score. Model three adjustment did not identify any variation in total HoNOS score reduction from baseline to follow up by the measures of App engagement. Model four found no effect of a diagnosis of ASD on the overall reduction. The expected HoNOS-LD total scores decreased by 0.65 standard deviations after the BiH intervention.

The normative analysis conducted in the original validation work estimated a mean reduction in HoNOS-LD of 2.4 over a 3-month period in 372 patients with a broad spectrum of learning disabilities attending 16 NHS Trusts (including 60 patients with a diagnosis of autism) [35]. The mean reduction in HoNOS-LD total score following the BiH intervention was significantly greater than expected based on the null hypotheses of a 2.4 change from the normative study (p=0.004).

Changes in individual HoNOS-LD component Scores

Specific changes were found for 'Self-Injurious Behaviours' (p=<0.001) with a decrease in self-harming behaviour among participants. Additionally, significant improvements were found in the median score for 'Memory and orientation' (p=<0.001), 'Communication problems in understanding' (p=<0.001), 'Occupation and activities' (p=<0.001) and 'Problems with relationships' (p=<0.001). These results indicate improvements in the ability to communicate, form relationships and develop positive social interactions through activity and occupation. A significant change was also noted in 'Problems with eating and drinking' (p=0.001), suggesting a decrease. in negative eating patterns and behaviours (Table 4). 'Activities of Daily Living – outside of the home' (p=<0.04) also showed a positive significant decrease but did not meet the threshold for the Bonferroni correction (Table 4).

Changes in HoNOS-LD cluster scores

Five of seven clusters (Cluster 1: Behavioural problems, Cluster 2: Cognition, Cluster 3: Communication, Cluster 4: Mental state, Cluster 7: Social functioning) showed significant improvements in median score from baseline to follow-up when assessed against the Bonferroni corrected threshold of p<0.007 (Table 5). A trend towards improvement was also seen in the activities of daily living domain.

Qualitative analysis

All 10 randomly selected participants consented to take part in the interview. Thematic analysis was conducted on the 10 respondents' interviews. The themes and key example verbatim comments are provided in table 6

The emergent themes were:

Set up process of Brain in Hand (On-Boarding)

Participants voiced a positive experience with onboarding, particularly when the participant reported allocation of a specialist, who also disclosed that they were Autistic. 10% of interviewed participants reported issues with compatibility, where their technology device was not compatible with the BiH application. Useability was reported as simple, however, some expressed a need for an Information Technology (IT) ability assessment for all participants using BiH since some participants reported feelings of frustration during onboarding, when their high level of IT ability was not recognised. Some participants reported onboarding was lengthy and could have been condensed.

Building Confidence

Participants found BiH easy to use, and confidence grew as time went on. Confidence was particularly evident where participants discussed the importance of building a partnership with their specialist and how

this enabled them to experience personalised support that aided a development in self-awareness of their autism. Participants also reported an increased confidence in managing unplanned events using BiH as the support they received helped to breakdown unplanned events into manageable steps and reduce their sensory overload. Despite an increase in confidence expressed by many, some participants were still reliant on family, partners and friends even with BIH.

Traffic Light System and Self-Awareness (appendix 4)

Some participants reflected how the traffic light system supported a development in their own awareness of emotion.

For example, participants discussed that just being reassured that they had access to the traffic light feature prevented an escalation of their sensory overload, since it prompted them to stop, identify the emotion and encourage a positive mood. Participants were able to use this feature to think about personal coping strategies to relieve feelings of stress and feeling overwhelmed. They also discussed how the digital health tool enhanced their independence, through providing an additional support option if needed, which meant they did not solely rely on their current supporters outside of the intervention.

Suggested Developments by Participants

Participants suggested developments primarily within the traffic light system, suggesting the need for further opportunity to track their emotions within this feature of the app. The findings indicate that mood tracking and further options for pressing 'red' may be a benefit, as many reported anxieties with receiving a crisis call. Others reported just the act of pressing 'red' would support reflection and the activation of coping skills without the requirement for receiving a crisis call.

Participants also suggested further personalisation during onboarding, specifically regarding IT skill level.

Frustration was expressed with the calendar feature since it did not sync with their other apps and technology programmes. Participants also reported limitations within the BiH planning tool, including the ability to only view one day at a time, and the inability to plan for the future.

The requirement to log in during times of crisis led to participants reporting increased feelings of anxiety and frustration. A lack of accessibility was described, specifically as there was a requirement to sign in to access some parts of the app which prevented immediate access in times of crisis. This was seen as a clear limitation by some participants. Participants would also like more autonomy in editing and planning to enhance person centred bespoke usage.

Participants have suggested an opportunity to be able to reach out to other BiH users to gain peer support from each other.

Participants suggested a bank of autism support strategies would be useful to learn from other autistic people could allow them to build their own autism strategies.

Connectivity (Wi-Fi) can be limited in some areas. Participants described their experiences in public places such as shopping and town centres. Participants reported that in environments where autistic people may struggle the most, some retailers restrict Wi-Fi in their premises. Participants reported Brain in Hand was not available due to lack of Wi-Fi and poor connectivity in those areas. Participants expressed some features to be accessible without Wi-Fi. The cost of Broadband, IT Training and IT equipment needs to be considered, since participants feel this could be a barrier to accessing BiH and reduce accessibility for all autistic people.

Recommending to other Autistic People

Participants said they would recommend BiH to another autistic person, with many reporting they were given hope that digital health tools could support autistic people in teaching self-awareness and aiding education. One participant talked of their experience with personalisation, a favourite Spotify playlist was utilised and linked to help them through a sensory overload with a positive outcome. It was clear that participants who spend more time personalising the tool described experiencing more positive outcomes.

Participants who would recommend BiH did, however, say they would do so with caution, and that the app should be treated as an addition to current care, rather than a replacement. The need for enhanced commitment during set-up is needed to allow the app to be effective.

Some participants also reported that similar products should be made available with more choice.

Discussion

Autistic adults struggle with day-to-day engagement with society which increases their likelihood to have major mental health problems. Anxiety, in particular, due to the challenges of unpredictability of day-to-day stresses, is a common co-morbidity [39].

This prospective cohort study examined the use of BiH, a digital health tool for adults with level 1 ASD or bearing a high suspicion of it and it's impact on their mental well-being and quality of life. The current study aimed to examine BiH's capability to meet Level C (previous tier 3) of the NICE digital framework. [32] Its focus was to identify if BiH can allow autistic people to self-manage their difficulties and enable positive behaviour changes. This study employs a pragmatic clinical study design. [40] The study is designed to evaluate the effectiveness of BiH in real-life routine practice conditions to produce results that can be generalised and applied in routine community settings.

Autistic people are prone to anxiety. [5]. The anxiety is more a derivation of situation and environmental factors which autistic people find difficult to comprehend or navigate. [6] The study findings suggest that BiH when used for a minimum of 12 weeks can reduce day to day anxiety and improve quality of life. The significant decrease in anxiety observed on the HADS on 12 weeks of use of BIH suggests BiH is associated with users utilising it to engage positively with the environment which likely has had a positive impact on stress and anxiety. There were no significant improvements noted on change in depressive features. However, it could be argued that depression as a disorder is unlikely to respond within a 12-week period as, unlike autistic anxiety, it is not situational and likely requires more robust alternate therapeutic engagement.

More specifically, BiH improves meaningful communication, provides better engagement with occupation and day to day activities and improves meaningful relationships. It also appears to enable improved concentration and memory. There is a positive link of BiH's usage with reduction of self-harm and harmful eating practices. The overall effect size (0.65) of the impact of BiH seen on the quality-of-life measures of HONOS-LD suggests a strong relationship of BiH impacting positively on the quality of life of autistic people who chose to use BiH. These findings suggest that BiH provides a holistic intervention focused on improving the overall quality of life on the individual autistic person. User feedback showed users who used BiH for the study period not only benefitted from the intervention but were very satisfied overall with the full experience. In addition, a normative analysis undertaken by comparing the changes in HoNOS score in the present cohort with the original validation study showed significantly greater than expected reductions following the BiH interventions.

A third of the study cohort dropped out. This suggests that BiH is not suitable for all autistic people. In particular, those not in their own house and aged over 30 and who were less troubled by anxiety were less likely to engage with BiH. There could be various reasons for this. The lack of stability could prevent an autistic individual from having a routine in using the BiH. Those above 30 might have been digitally

excluded. Those who had less anxiety might have perceived themselves to be currently settled and thus found little use for the BiH interventions. It is important to recognise that further work needs undertaking to understand these dropout rates.

Limitations of the study

The study design did not include a randomised control group, which was acknowledged as a limitation. Therefore, comparisons were not able to be made between the effectiveness of the intervention and treatment as usual. However, given the study population was heterogenous and the intervention a complex digital tool, a Randomised Control Trial would be challenging. Use of an observational pre-post design allowed each participant to serve as their own control when assessing effectiveness. The possibility that the changes observed may be influenced by external confounders cannot be excluded but this was mitigated against by making comparisons to normative data for the HoNOS-LD outcome. The HoNOS-LD was primarily designed for people with a learning disability (LD); however the study used the HoNOS-LD to measure changes in clinical outcome for people with ASD, or suspected ASD, whilst excluding those with LD. The HoNOS -LD scale was still deemed the most appropriate measure to determine how digital health tools have impacted upon clinical outcomes, which in turn effects quality of life. An additional limitation was the missed opportunity to collect additional demographic data such as ethnicity and education levels. This would have allowed further analysis between ethnic groups and provided insight to whether education levels have a role in digital engagement.

Mapping BiH to the NICE digital health technologies framework

The current study supports BiH having the minimum needed evidence to meet the research effectiveness standards for Tier C of the NICE Digital health technologies [32]. It thus could be asserted that BiH provides Tier C evidence-based interventions to self-manage anxiety, mental well-being and risk behaviours in level 1 people with ASD (table7).

Conclusion

Implications for clinical practice

BiH has demonstrated effectiveness for behaviour change and self-managed functions in level 1 autistic people who choose to use it regularly. It has enabled significant improvement in quality of life of autistic people with significant reductions in anxiety and self-harm. There were no adverse or negative events reported and has been considered safe to use.

Implications for policy

BiH economic evaluation needs consideration. There is currently a recognised challenge for autistic people to access social and health care support. [17] For many this is a low-level support more to do with understanding their environment which is the principal challenge in level 1 autism. BiH can fill this gap and afford timely help and support. This not only reduces the risks of psychological worsening for autistic individuals, but it also improves their quality of life and reduces the public health burden and social care dependency.

Implications for technology

The current study supports BiH to meet the minimum evidence needed to satisfy level C of the NICE digital evidence framework. [32]. It would be recommended to use the evidence to apply for Level 3/C ORCHA validation.

Implications for research

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BiH has shown itself to be effective for a group of autistic individuals but not for another subset. More research needs undertaking on whether BiH can be "adjusted" to encompass the needs of those who dropped out. This was a three-month study. It would be helpful to see if the improvements identified by using BiH sustain for longer periods of time.

Reference List

1. National Institute for Health and Care Excellence. Autism in adults [Internet]. [London]: NICE; 2020. (Clinical knowledge summary). Available from: https://cks.nice.org.uk/topics/autism-in-adults/ (accessed 03/07/2022)

2. Fletcher-Watson S, Happe F. Autism: A New Introduction to Psychological Theory and Current Debates. Taylor and Francis, Routledge, London 2019. Ebook No: 9781315101699. https://doi.org/10.4324/9781315101699. [Accessed online 11th March 2021].

3. Russell, G., Stapley, S., Newlove-Delgado, T., Salmon, A., White, R., Warren, F., Pearson, A. and Ford, T, Time trends in autism diagnosis over 20 years: a UK population-based cohort study. J Child Psychol Psychiatr, (2022) 63: 674-682. https://doi.org/10.1111/jcpp.13505

4. Lai MC, Kassee C, Besney R, Bonato S, Hull L, Mandy W et al. Prevalence of co-occurring mental health diagnoses in the autism population: a systematic review and meta-analysis. The lancet. psychiatry,2019, 6(10), 819–829. https://doi.org/10.1016/S2215-0366(19)30289-5.

5. National Autistic Society. Good Practise Guide for Professionals. 2020. https://s2.chorus-mk.thirdlight.com/file/24/asDKIN9as.klK7easFDsalAzTC/NAS-Good-Practice-Guide-A4.pdf . (Accessed online 24th May 2022).

6. Shankar R, Smith K, Jalihal V. Sensory processing in people with Asperger syndrome. Learning Disability Practice. 2012: 16 (2) 22-27. doi:10.7748/ldp2013.03.16.2.22.e658. [Accessed online 11th May 2022].

7. Blanchard A, Chihuri S, Diguiseppi CG, Li G. Risk of self-harm in children and adults with autism spectrum disorder: A systematic review and meta-analysis. Jama netw open. 2021, 4 (10): e2130272. doi:10.1001/jamanetworkopen.2021.30272.

8. Cassidy S, Au-Yeung S, Robertson A, Cogger-Ward H, Richards G, Allison C et al. Autism and autistic traits in those who died by suicide in England. British journal of psychiatry. 2022. https://doi.org/10.1192/bjp.2022.21.

9. Richard G, Kenny R, Griffiths S, Creese B, Aarsland D, Charlton et al. Autistic traits in adults who have attempted suicide. Molecular Autism 2019: 10, 26. https://doi.org/10.1186/s13229-019-0274-4.

10. Hirvikoski T, Mittendorfer-Rutz E, Boman M, Larsson H, Lichtenstein P, Bölte S. Premature mortality in autism spectrum disorder. Br J Psychiatry. 2016 208(3):232–8.

11. Rydzewska E, Hughes-McCormack LA, Gillberg C, Henderson A, MacIntyre C, Rintoul J et al. Prevalence of long-term health conditions in adults with autism: observational study of a whole country population. BMJ Open. 2018 Sep 1:8(8):e023945. doi: 10.1136/bmjopen-2018-023945. Erratum in: BMJ Open. 2019 Feb 22:8(11):e023945corr1. PMID: 30173164: PMCID: PMC6120653.

12. Sharpe RA, Curry W, Brown R, Shankar R. A public health approach to reducing health inequalities among adults with autism. The British journal of general practice : the journal of the Royal College of General Practitioners,2019: 69(688), 534–535. https://doi.org/10.3399/bjgp19X706133.

13. Murphy CM, Wilson CE, Robertson D M, Ecker C, Daly EM, Hammond N. et al. Autism spectrum disorder in adults: diagnosis, management, and health services development. Neuropsychiatric disease and treatment, 2016: 12, 1669–1686. https://doi.org/10.2147/NDT.S65455.

14. Oakley B. COVID exacerbates healthcare inequalities for autistic people. Kings College London. Institute of Psychiatry, Psychology & Neuroscience 2021.https://www.kcl.ac.uk/news/covid-exacerbates-healthcare-inequalities-for-autistic-people.

15. British Medical Association. NHS backlog data analysis, Analysis of monthly data releases by NHS England to highlight the growing backlogs across the NHS - including operations data, cancer waiting list GP referrals and A&E waiting times. 2022, https://www.bma.org.uk/advice-and-support/nhs-delivery-and-workforce/pressures/nhs-backlog-data-analysis.

16. Charlesworth A, Johnson P, Firth Z, Gershlick B, Watt T, Kelly E et al. Securing the future: funding health and social care to the 2030s. Cost pressures on the NHS are set to grow: a long-term

funding solution is needed, likely through tax increases. The Health Foundation 2018 https://www.health.org.uk/publications/reports/securing-the-future-funding-health-and-social-care-to-the-2030s.

17. Sharpe RA, Curry W, Brown R, Shankar R. A public health approach to reducing health inequalities among adults with autism. The British journal of general practice : the journal of the Royal College of General Practitioners,2019: 69(688), 534–535. https://doi.org/10.3399/bjgp19X706133.

18. Buescher A, Cidav Z, Knapp M, Mandell D. Costs of autism spectrum disorders in the United Kingdom and the United States. Jama paediatrics. 2014 Aug:168(8):721-8. doi: 10.1001/jamapediatrics.2014.210. PMID: 24911948.

19. Knapp M, Romeo R, Beecham J. Economic cost of autism in the UK. Autism. 2009 May:13(3):317-36. doi: 10.1177/1362361309104246. PMID: 19369391.

20. NHS Digital. Why digital inclusion matters to health and social care. 2022: https://digital.nhs.uk/about-nhs-digital/our-work/digital-inclusion/digital-inclusion-in-health-and-social-care. (Accessed online 6th May 2022).

21. Rogge N, Janssen J. The Economic Costs of Autism Spectrum Disorder: A Literature Review. J Autism Development Disorder, 2019: 49, 2873–2900 https://doi.org/10.1007/s10803-019-04014-z.

22. Rothwell C. Research and Information Service Briefing Paper. National Irish Assembly. 2020. http://www.niassembly.gov.uk/globalassets/documents/raise/publications/2017-2022/2021/finance/0821.pdf.

23. five-year NHS autism research strategy for England

24. Health Education England. The Topol Report. Preparing the healthcare workforce to deliver the digital future The Topol Review An independent report on behalf of the Secretary of State for Health and Social Care. The Topol Review — NHS Health Education England (hee.nhs.uk 2019). (Accessed online 30th May 2022).

25. Lemmi, V, Knapp, M and Ragan, I. The autism dividend, reaping the rewards of better investment. National autism project 2020. https://nationalautistictaskforce.org.uk/wp-content/uploads/2020/02/autism-dividend-report.pdf.

26. Fahy N, Williams G. Use of digital health tools in Europe Before, during and after COVID-19 . COVID-19 Health System Response Monitor Network POLICY BRIEF 42.The European Observatory on Health Systems and Policies. 2021. Demark. file:///C:/Users/summeria/Downloads/Policy-brief-42-1997-8073-eng.pdf.

27. SBRI. Scaling a digital support system to reduce workforce pressure. SBRI Healthcare. 2019: https://sbrihealthcare.co.uk/company/brain-in-hand-ltd/. (Accessed online 10th May 2022).

28. Horton T, Hardie T, Mahadeva S, Warburton W. Securing a positive health care technology legacy from COVID-19. The Health Foundation 2021. https://www.health.org.uk/publications/long-reads/securing-a-positive-health-care-technology-legacy-from-covid-19. (Accessed online 11th May 2022).

29. Kim J, Nguyen T, Gipson S, Shin, AL, Torous J. Smartphone Apps for Autism Spectrum Disorder—Understanding the Evidence journal. Technology in behaviour science. 2017: 3, 1–4 . https://doi.org/10.1007/s41347-017-0040-4. [Accessed online 19th March 2021].

30. Mason D, McConachie H, Garland D, Petrou A, Rodgers J, Parr, JR. Predictors of quality of life for autistic adults. Autism research : official journal of the International Society for Autism Research, 2018 :11(8), 1138–1147. https://doi.org/10.1002/aur.1965.

31. American Psychiatric Association. Diagnostic and statistical manual of mental disorders. (2013) (5th edn.). Washington, DC: American Psychiatric Association.

32. Von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP; STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. Lancet. 2007 Oct 20;370(9596):1453-7. doi: 10.1016/S0140-6736(07)61602-X. PMID: 18064739. (Accessed Online 21st March 2022).

33. NICE. Evidence standards framework (ESF) for digital health technologies. 2021: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies. (Accessed online May 11th 2022).

34. Zigmond A, Snaith R. The hospital anxiety and depression scale. Acta Psychiatr Scand. 1983: 67:361–370. doi: 10.1111/j.1600-0447.1983.tb09716.x. https://pubmed.ncbi.nlm.nih.gov/6880820

35. Roy A, Matthews H, Clifford P, Fowler V, Martin DM. Health of the Nation Outcome Scales for People with Learning Disabilities (HoNOS-LD). Br J Psychiatry. 2002 Jan:180:61-6. doi: 10.1192/bjp.180.1.61. PMID: 11772853.

36. Roy, A., Matthews, H., Clifford, P., Fowler, V., & Martin, D. (2002). Health of the Nation Outcome Scales for People with Learning Disabilities (HoNOS–LD). British Journal of Psychiatry, 180(1), 61-66. doi:10.1192/bjp.180.1.61

37. Wigham S, Ingham B, Le Couteun A. Berney T. Ensum I, Parr, J. Development and initial utility of the autism clinical interview for adults: A new adult autism diagnostic measure. Autism in adults: 2019: 2 (1). https://doi.org/10.1089/aut.2019.0052. [Accessed 29th online January 2021].

38. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative research in psychology. 2006 3 (2) 77-101. https://doi.org/10.1191/1478088706qp063oa.

39. Birks M, Mills J. Grounded theory: a practical guide. 2015, 2nd ed. London: SAGE.

40. Jenkinson R, Milne E, Thompson A. The relationship between intolerance of uncertainty and anxiety in autism: A systematic literature review and meta-analysis. Autism. 2020 Nov;24(8):1933-1944. doi: 10.1177/1362361320932437. Epub 2020 Jun 22. PMID: 32564625; PMCID: PMC7539603

41. Patsopoulos NA. A pragmatic view on pragmatic trials. Dialogues Clin Neurosci. 2011;13(2):217-24. doi: 10.31887/DCNS.2011.13.2/npatsopoulos. PMID: 21842619; PMCID: PMC3181997.

Appendix 1

The Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM 5) describes three levels of ASD depending on how severe their disorder is and how much support they need in their daily life. The levels range from least to most severe, with ASD level 1 describing someone with symptoms on the milder end of the spectrum while level 3 has the most severe level of ASD symptoms. ASD level 1 is predominated by individuals who have difficulty initiating social interactions and for whom organisation and planning can hamper their independence. Level 1 autistic individuals, without proper support, will display noticeable impairments in social communication. Common behaviours in autistic individuals with level 1 include:

- Inflexibility in behaviour and thought

- Difficulty switching between activities

- Problems with executive functioning which hinder independence

- Atypical response to others in social situations

- Difficulty initiating social interactions and maintaining reciprocity in social interaction

Appendix 2

Measures

Hospital Anxiety and Depression Scale

The HADS is a self-report measure identifying symptoms of depression and anxiety within the last 7 days (Zigmond & Snaith 1983). The HADS is recommended to be used to detect symptoms of depression and anxiety in clinical practice (NICE 2022). The HADS is a valid and reliable self-report measure that is widely used for detecting anxiety and depressive disorders in the community, as well as being suitable for administration on autistic adults (GL Assessments 2021, Bocerean & Dupret 2014, Bjelland et al 2002).

Health of the Nation Outcome Scale – Learning Disabilities.

The HoNOS-LD is designed for use with people with a learning disability, regardless of the degree of their disability (Royal College of Psychiatrists 2021, Roy et al 2002). HoNOS-LD has been tested for inter-rater reliability, convergent reliability, validity of change in quality of life and acceptability for use with Autistic people (Roy et al 2018).

The HoNOS—LD is designed for use with people with a learning disability and with added mental health needs, irrespective of the degree of their disability. Its primary aim is to measure change in an individual over two or more points in time as a measurement of outcome for therapeutic interventions. It measures change in the level of problems that a person has had and is not intended to be a comprehensive description of the individual. Like the generic HoNOS, HoNOS—LD may be used as a simple 'present state' profile for use by clinicians for their own purposes and could also be used, after aggregation and anonymisation, for epidemiological and administrative purposes.

The HoNOS—LD measures global outcomes and not inputs. It is not a rating for disability alone. The scale has items designed to measure areas of functioning that are relatively stable, and items measuring more transient phenomena that are more likely to change as a result of treatment.

Although the level of support that an individual receives will usually have a significant impact on performance, HoNOS—LD rates performances with the existing support, and not the individual's potential or the cause of the disability. Since it is intended for use in assessing global changes in those undergoing treatment, interventions in any area can lead to changes in several areas of functioning. It may be that a combination of inputs would produce the best outcome for some individuals or groups of people. The HoNOS—LD is able to measure no change, or deterioration, as well as improvement. HoNOS-LD is an appropriate instrument for measuring outcome in people with learning disabilities with additional mental health needs.

Appendix 3

Brain in Hand

<div align="center">

Semi Structured Questions

</div>

Date:……/……./ 2021

Interviewer: ………….   Participant ID Code: (……………)   Site ID Code (……..)

In person: (Telephone) (Video) (Audio)……………………….

Start Time:…………….   End Time:…………….

1. **Using Brain in Hand:**

   Q) What was your experience of using Brain in Hand?

   Prompts:

   - Can you describe how confident you felt using Brain in Hand?

   - Can you tell me how long it took you to feel confident in using Brain in Hand?

   - What was your experience of the one to one support you received in using Brain in Hand?

2. **Plan your Day Experience:**

   Q) Can you tell me how Brain in Hand has helped you plan your day?

   Prompts:

   - Do you feel more able to plan your day when using Brain in Hand?

   - What do you find difficult in planning your day?

   - Can you tell me about a plan for the day that helped you when using Brain in Hand?

3. **Independence:**

   Q) Can you explain how Brain in Hand has helped you with your independence?

   Prompt:

   - What was your experience of independence when using Brain in Hand?

   - Can you talk about a time when Brain in Hand helped you to feel more independent?

20

- Can you explain if you have relied on family, friends or others for support before using the Brain in Hand App and how this might have changed?

- Can you tell me about a time when you used the Brain in Hand App to support your independence, which previously you would have used family, friend or other to support you or from other services?

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4. **Coping Skills Experience:**

Q) Can you tell me how you coped with change by using your coping skills from the Brain in Hand App?

Prompt:

- Tell me about your experience of using your coping skills from the Brain in Hand App?

- What differences in your coping skills have you noticed when using the Brain in Hand?

- Tell me how you would cope with change if you did not have the Brain in Hand App?

-

5. **Anxiety experience:**

Q) What is your experience of anxiety when using Brain in Hand?

Prompt:

- Can you tell me how Brain in Hand has helped you when you felt anxious?
- Can you explain how your anxiety felt before you used the Traffic Light System?
- Can you explain how your anxiety felt after seeking support from the Traffic Light System?
- What was your experience of receiving support from Brain in Hand App when feeling anxious?
- When using Brain in Hand App, can you explain any differences in your anxiety?
- If you did not have the Brain in Hand App, how would you cope with your anxiety? Would you seek support from other services that you now don't need to?
- How has Covid 19 isolation affected your anxiety?

6. **Mood Experience:**

Q) How would you describe your mood after using Brain in Hand App?

Prompt:
- How would you describe your mood today?
- How would you describe your mood before using Brain in Hand?
- Can you explain how your mood has been supported when using Brain in Hand?
- Can you give me an example of when Brain in Hand helped you cope with a low mood?
- Can you explain how you would cope without using the Brain in Hand App?
- Can you explain if Covid 19 has impacted on your mood and the use of Brain in Hand App?

7. **New Activities and Opportunities:**

Q) Can you tell me about any new activities or opportunities you have started in the last three months?

Prompt:
- What was your experience of attending a new activity with Brain in Hand support?

- Can you explain how Brain in Hand has supported you when going to new activities or opportunities?

- Would you be able to start new activities without support and could you explain what support you would need to attend an activity?

- What was your experience of accessing new activities during Covid 19?

8. **Experience of Using Telephone Support?**

Q) Can you discuss your experience of accessing the Brain in Hand telephone support line?

Prompt:
- Tell me how you felt when receiving telephone support?

- Can you explain how having access to a 24 hour helpline has helped you? What might you have done if you couldn't have called the helpline?

- Can you explain any difficulties you experienced in accessing telephone support?

9. **Benefits of using Brain in Hand:**

Q) What do you feel has benefited you most in using Brain in Hand?

Prompt:

1. My Anxiety.
2. My Planning Skills.
3. My Coping Skills.
4. My Mood.
5. My Problem Solving.
6. My ability to cope better.
7. My Access to 24 hour Support.
8. My Independence.

10. **How would you describe your life now: if you did not have the opportunity to use the Brain in Hand App?**

11. **What improvements would you make to Brain in Hand and would you recommend the Brain in Hand App to other autistic people?**
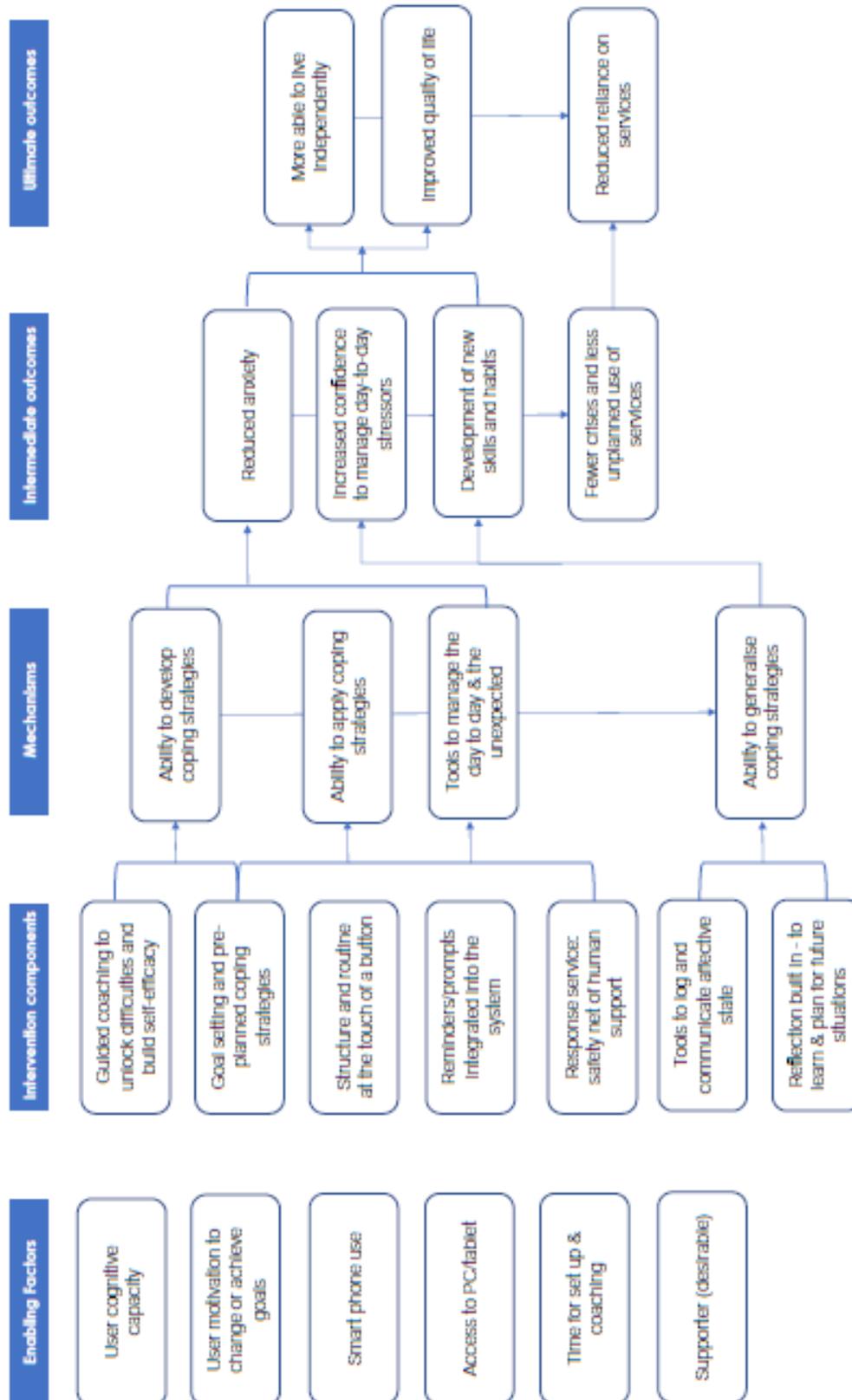
Appendix 4

Logic Model

A logic model diagram with five columns (rotated sideways on the page):

Enabling Factors
- User cognitive capacity
- User motivation to change or achieve goals
- Smart phone use
- Access to PC/tablet
- Time for set up & coaching
- Supporter (desirable)

Intervention components
- Guided coaching to unlock difficulties and build self-efficacy
- Goal setting and pre-planned coping strategies
- Structure and routine at the touch of a button
- Reminders/prompts integrated into the system
- Response service: safety net of human support
- Tools to log and communicate affective state
- Reflection built in – to learn & plan for future situations

Mechanisms
- Ability to develop coping strategies
- Ability to apply coping strategies
- Tools to manage the day to day & the unexpected
- Ability to generalise coping strategies

Intermediate outcomes
- Reduced anxiety
- Increased confidence to manage day-to-day stressors
- Development of new skills and habits
- Fewer crises and less unplanned use of services

Ultimate outcomes
- More able to live independently
- Improved quality of life
- Reduced reliance on services

Table 1. Sociodemographic characteristics of Participants

Characteristic	Overall (n=99)	Waiting List (n=47)	Formal Diagnosis (n=52)	p-value
Age				0.67
19 - 30	39	19	20	
31 - 40	24	11	13	
41 - 50	10	5	5	
51 - 60	19	10	9	
61-70	6	1	5	
Missing	1	1	0	
Employment				0.85
Employed	47	21	26	
Unemployed	38	19	19	
Other	14	7	7	
Support				1.00
Supported	32	15	17	
Not Supported	62	30	32	
Other	5	2	3	
Accommodation				0.31
Rented	52	21	31	
Own Home	37	20	17	
Other	10	6	4	
Relationship status				0.90
Married/partner	50	25	25	
Divorced	40	3	3	
Single	6	18	22	
Missing	3	1	2	

Table 2. Changes in HONOS-LD Scores

	N	Mean (SD)	Median (IQR)
Baseline Score	99	18.7 (7.6)	20 (9.0)
Follow Up Score	66	13.9 (8)	12.5 (10)
Change Score	64	-5.7 (8.7)	-6 (12.5)

	N	Mean (SD)	Median (IQR)

Table 3 – Drop-out Rate Scores

Variable		N	Odds ratio	p
Age	19-30	39		Reference
	31-40	24		3.68 (1.00, 14.53) 0.054
	41-50	10		3.48 (0.60, 20.88) 0.160
	51-60	19		3.79 (0.85, 18.65) 0.088
	61-80	6		1.33 (0.12, 11.40) 0.796
Accommodation	Own home	37		Reference
	Other	9		8.75 (1.30, 65.07) 0.028
	Rented	52		4.12 (1.36, 14.06) 0.017
HADS_Anxiety		98		0.41 (0.23, 0.68) 0.001

0.2 0.5 1 2 5 10 20 50

Table 4. Changes in individual HONOS-LD component Scores

Item	Baseline Mean	Follow-up Mean	P Value
1. Behaviour towards others	0.89	0.85	0.37
2. Self-injurious behaviour	1.30	0.58	**<0.001**
3. Other mental and behaviour problems	1.57	1.42	0.16
4. Attention and concentration	1.25	1.05	0.08
5. Memory and orientation	0.88	0.47	**<0.001**
6. Communication problems in understanding	1.00	0.39	**<0.001**
7. Communication problems in expression	0.86	0.59	**0.02**
8. Hallucinations and delusions	0.09	0.08	1.00
9. Mood changes	1.63	1.38	**0.02**
10. Sleep Problems	1.66	1.39	**0.04**
11. Problems with eating and drinking	1.04	0.68	**<0.001**
12. Physical problems	0.62	0.62	0.73
13. Seizures	0.07	0.06	0.37
14. ADL at home	1.18	0.94	0.11
15. ADL outside the home	1.22	1.05	**0.04**
16. Level of self-care	0.86	0.71	0.16
17. Problems with relationships	1.53	0.89	**<0.001**
18. Occupation and activities	1.12	0.74	**<0.001**

Table 5. Changes in HONOS-LD cluster scores

Cluster	Baseline Median	Follow-up Median	P Value
1. Behavioural problems, items 1-3	5.0	3.5	0.001
2. Cognition, items 4 and 5	2.0	1.5	0.003
3. Communication, items 6 and 7	2.0	1.0	0.001
4. Mental state, items 8-11	4.0	4.0	<0.001
5. Physical problems, items 12 and 13	0.0	0.0	0.61
6. Activities of daily living, items 14-16	3.0	2.0	0.01
7. Social functioning, items 17 and 18	2.0	1.0	<0.001

Table 6: Developed Themes

Themes	Quotes
Set up process of Brain in Hand (On-Boarding)	*"It could have quite easily of been condensed"*
Building Confidence	*'At supermarkets where I get overwhelmed, for example, even if I didn't use it, it just gave me that little bit of extra confidence I think'* *"Planning is the biggest thing for me"* *"I've been mainly using my parents for symptoms of anxiety".*
Traffic Light System and Self-Awareness	*"Because I don't understand my feelings that well, the traffic light system has been a blessing"* *"I've mostly used um the traffic lights system just to keep track of my mood"*
Suggested developments by participants	*"I'm just gonna use the red traffic light and Just the act of doing that kind of pulled me out of that cycle".* *"I have to program everything in manually and then analyse it, whereas if I could just upload my calendar to it then I would find that a lot easier".* *Unfortunately, on the app you can only see daily, so it's not very helpful when you're trying to plan a week".*
Recommending to other Autistic people	*'I would recommend it to people…I think while people are on the waiting list - brain in hand could then be expanded to more of an educational element as well because people will be able to self-manage a lot better without getting as distressed'.*
Covid-19 and Isolation Experience	*'Loved It", "Enjoyed Lockdown", "Home was a safe place"* *"I quite enjoyed the lockdowns. Um. But I think it's because I didn't have to deal with people".* *"I didn't particularly mind being inside. It was more when we started to go out again that the anxiety hit"*

Table 7 Comparision of BiH intervention to the NICE digital framework level C

Evidence category	Nature of minimum accepted evidence	BiH research study findings
Demonstrating effectiveness for preventative behaviour change or self-manage functions	High-quality observational or quasi-experimental studies demonstrating relevant outcomes. These studies should present comparative data. Comparisons could include: relevant outcomes in a control group use of historical controls routinely collected data. Relevant outcomes may include: behavioural or condition-related user outcomes such as reduction in smoking or improvement in condition management evidence of positive behaviour change user satisfaction.	Cohort study with a normative analysis to original validation of the used quality of life tool. Demonstrated significant reductions in overall HONOS scores and levels of Anxiety on HADS User satisfaction of those who competed the study was very high
Use of appropriate behaviour change techniques (if relevant)	Be able to show that the techniques used in the DHT are: • consistent with recognised behaviour change theory and recommended practice (aligned to guidance from NICE or relevant professional organisations) • appropriate for the target population.	BiH targets core symptoms of ASD. It help planning and decision making and managing anxiety. There was recognition of significant change on use of BiH in these symptom profiles for autistic people
Reliable information content	Be able to show that any health information provided by the DHT is: • valid (aligned to best available sources, such as NICE guidance, relevant professional organisations or	BiH is ORCHA level 2 certifed

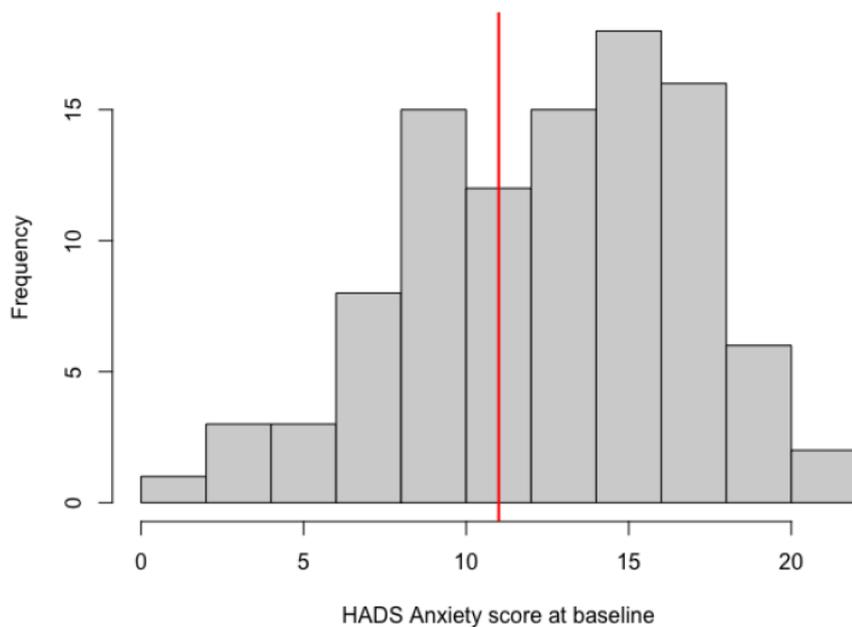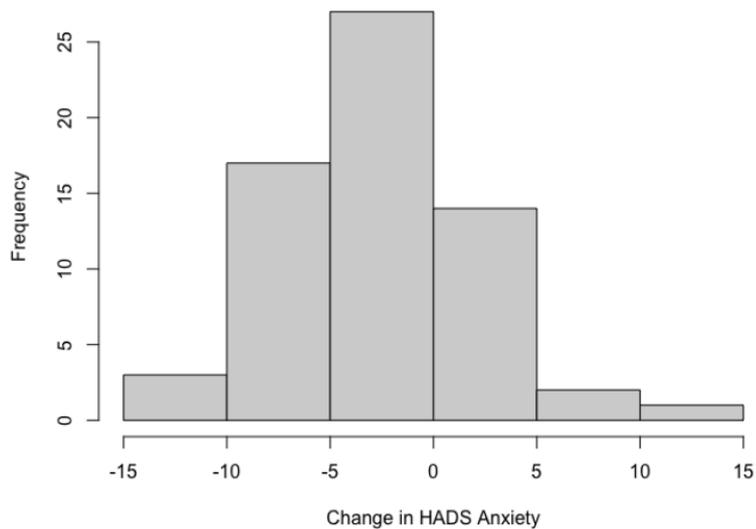|		
	recognised UK patient organisations, and appropriate for the target population) • accurate • up to date • reviewed and updated by relevant experts at defined intervals, such as every year • sufficiently comprehensive	

Figure 1A – Baseline scores for HADS anxiety

Figure 1B – Change in HADS anxiety at follow up

Supplementary Information 1

Severity level	Social communication	Restricted, repetitive behaviours
Level3 "Requiring very substantial support"	Severe deficits in verbal and nonverbal social communication skills cause severe impairments in functioning, very limited initiation of social interactions, and minimal response to social overtures from others. For example, a person with few words of intelligible speech who rarely initiates interaction and, when he or she does, makes unusual approaches to meet needs only and responds to only very direct social approaches	Inflexibility of behaviour, extreme difficulty coping with change, or other restricted/repetitive behaviours markedly interfere with functioning in all spheres. Great distress/difficulty changing focus or action.
Level2 "Requiring substantial support"	Marked deficits in verbal and nonverbal social communication skills; social impairments apparent even with supports in place; limited initiation of social interactions; and reduced or abnormal responses to social overtures from others. For example, a person who speaks simple sentences, whose interaction is limited to narrow special interests, and how has markedly odd nonverbal communication.	Inflexibility of behaviour, difficulty coping with change, or other restricted/repetitive behaviours appear frequently enough to be obvious to the casual observer and interfere with functioning in a variety of contexts. Distress and/or difficulty changing focus or action.
Level1 "Requiring support"	Without supports in place, deficits in social communication cause noticeable impairments. Difficulty initiating social interactions, and clear examples of atypical or unsuccessful response to social overtures of others. May appear to have decreased interest in social interactions. For example, a person who is able to speak in full sentences and engages in communication but whose to- and-fro conversation with others fails, and whose attempts to make friends are odd and typically unsuccessful.	Inflexibility of behaviour causes significant interference with functioning in one or more contexts. Difficulty switching between activities. Problems of organization and planning hamper independence.