

# Brain-In-Hand technology for adults with acquired brain injury: A convergence of mixed methods findings

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#### Abstract

**Introduction:** Individuals with acquired brain injury may find it difficult to self-manage and live independently. Brain-in-Hand is a smartphone app designed to support psychological problems and encourage behaviour change, comprised of a structured diary, reminders, agreed solutions, and traffic light monitoring system.

**Aim:** To evaluate the potential use and effectiveness of Brain-in-Hand for self-management in adults with acquired brain injury.

**Methods:** A-B mixed-methods case-study design. Individuals with acquired brain injury (n = 10) received Brain-in-Hand for up to 12 months. Measures of mood, independence, quality of life, cognition, fatigue, goal attainment, participation administered at baseline, 6 and 12 months. Semi-structured interviews conducted with acquired brain injury participants (n = 9) and healthcare workers (n = 3) at 6 months.

**Results:** Significant increase in goal attainment after 6 months use (t(7) = 4.20, p = .004). No significant improvement in other outcomes. Qualitative data suggested improvement in anxiety management. Contextual (personal/environmental) factors were key in influencing the use and effectiveness of Brain-in-Hand. Having sufficient insight, appropriate support and motivation facilitated use.

**Conclusions:** Brain-in-Hand shows potential to support acquired brain injury, but further work is required to determine its effectiveness. Context played a pivotal role in the effectiveness and sustained use of Brain-in-Hand, and needs to be explored to support implementation.

#### **Keywords**

rehabilitation, smartphone app, smart technology, brain injury, self-management, independent living, assistive technology

## Introduction

Acquired brain injury is a heterogeneous condition resulting in cognitive, emotional and behavioural impairments,<sup>1–3</sup> which are often difficult to predict and make long-term rehabilitation challenging. Acquired brain injury is the leading cause of death and disability in young adults<sup>4</sup> and over one million people live with the long-term consequences of injury.<sup>5,6</sup> Acquired brain injury can have a detrimental impact on quality of life, limiting independence and restricting participation in daily activities.<sup>7,8</sup> Individuals <sup>1</sup>Centre for Academic Primary Care, Applied Health Research Building, University of Nottingham School of Medicine, Nottingham, UK <sup>2</sup>Centre for Rehabilitation & Ageing Research Injury, Inflammation and Recovery Sciences, School of Medicine University of Nottingham, Nottingham, UK

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often find it difficult to self-manage their condition, meaning they rely on others to support them in daily activities.<sup>9</sup> A lack of self-awareness, defined as '*the inability to recognise deficits resulting from one's injury*',<sup>10</sup> may impact on a person's ability to self-manage and set appropriate goals. Self-management is important as people with acquired brain injury need to be able to recognise their limitations and make informed decisions, without the support of others.<sup>11</sup>

The multifaceted nature of acquired brain injury means that rehabilitation interventions need to be individually tailored. Although many smart technologies exist to support some problems experienced following acquired brain injury, such as cognitive impairment, there is insufficient evidence to support the use of personal smart technologies for improving clinical outcomes in this population.<sup>12</sup> There are also multiple known challenges of implementing such interventions in complex settings like the UK National Health Service (NHS). Some of the barriers faced when implementing these technologies include resistance to change from traditional practice among therapists<sup>13</sup> and the translation of knowledge from technology developers to clinicians.<sup>14</sup> There is a need for effective rehabilitation interventions that support independent living and selfmanagement post-injury, which can be tailored to different needs and settings. With anticipated growth in the number of hospital admissions, alongside increasing social care costs, interventions need to focus on reducing societal pressure and health and social care reliance.

Brain-in-Hand is a smartphone application (app) that has been implemented in autism and mental health settings. Brain-in-Hand supports users by providing a structured daily routine for tasks and problem situations (see Figure 1 for summary). The technology was specifically engineered to support the management of persistent emotional and behavioural problems such as anxiety and depression - commonly seen in people with acquired brain injury. Users are able to selfmonitor problems (e.g. anxiety, fatigue) using a traffic light system. Any activity is sent from the app to an online 'cloud' in real time, which can be reviewed by the user and nominated mentor(s) (e.g. treating occupational therapist).

The aim of this study was to evaluate the potential use and effectiveness of Brain-in-Hand for adults with acquired brain injury. The specific objectives were to:

- 1. Identify barriers and facilitators to Brain-in-Hand use.
- 2. Determine whether Brain-in-Hand use was associated with improved outcomes related to goal attainment, mood, functional independence, quality of life, cognition, fatigue and participation.
- 3. Evaluate the acceptability of Brain-in-Hand from the perspective of people with acquired brain injury and healthcare workers after 6months' use.

#### Methods

A mixed methods A-B case design was used. Participants were recruited across three UK NHS sites and local charities for people with acquired brain injury between July 2016 and March 2017. Ethical approval was granted by NRES Committee East Midlands Nottingham 2, reference number 16/EM/0141. Participants with acquired brain injury were recruited by one author (JK). The initial approach was from a member of the NHS usual care team – e.g. an occupational therapist, or by a charity volunteer. Participants with acquired brain injury were also identified and approached by independent sector therapists, solicitors and case managers. Potential participants were informed of all aspects pertaining to their participation in the study (quantitative and qualitative data collection methods). For those interested, a visit was organised (face-to-face or over the phone) with the researcher, who took written informed consent.

Participants were both people with an acquired brain injury and healthcare workers. People with a brain injury were included if they were: (1) between 18 and 65 years of age; (2) diagnosed with an acquired brain injury; (3) at least 3 months post-injury/stroke; (4) had a smartphone and were competent at using it, and (5) had at least one problem as a result of their acquired brain injury that potentially limited their functional independence. People with communication difficulties resulting from acquired brain injury (e.g. severe aphasia) with no support from a relative or carer were excluded, as this may have limited participation in study activities such as setting up the device and the interviews. Healthcare workers were eligible to participate if they were treating or supporting a person with acquired brain injury (e.g. occupational therapist, support worker) who was participating in the study, and consented to participate.

As this was a series of case studies, no power calculation was performed. We aimed to recruit up to 15 people with acquired brain injury to take part in the case studies; a number considered sufficient to reach data saturation,<sup>15</sup> as enough information would be obtained to inform the design of a subsequent study (e.g. feasibility trial). Given the indepth nature of case studies, a sample size of at least five is recommended.<sup>16</sup>

Quantitative data were collected from acquired brain injury participants at various time points. The measures included: Hospital Anxiety and Depression scale (HADS)<sup>17</sup>; Nottingham Extended Activities of Daily Living (NEADL)<sup>18</sup>; Multiple Sclerosis Neuropsychological Screening Questionnaire (MSNQ)<sup>19</sup>; EuroQol EQ-5D-5 L<sup>20</sup>; Community Integration Questionnaire (CIQ)<sup>21</sup>; Fatigue Assessment Scale (FAS).<sup>22</sup> All measures were administered at baseline (time of consent), 6 and 12 months post-intervention. Two questionnaires (Hospital Anxiety

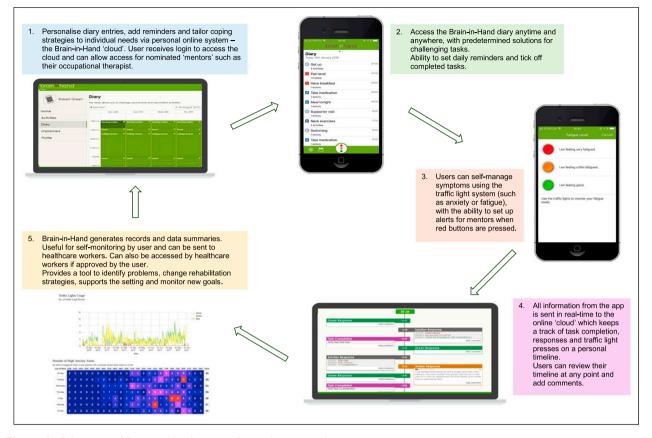


Figure 1. Schematic of Brain-in-Hand system, from planning to data monitoring.

and Depression scale & Nottingham Extended Activities of Daily Living) were administered fortnightly for 12 weeks (baseline, weeks 2, 4, 8, 10 and 12). Brain-in-Hand was introduced at week six to enable an average baseline score (from three different time points) to be calculated prior to receiving the intervention. The same measures were administered fortnightly for 6 weeks following the introduction of Brain-in-Hand to enable the identification of any changes in mood or activities of daily living/independence after receiving the intervention. The intervention was introduced in the middle of this fortnightly measurement period. Rasch versions of the Hospital Anxiety and Depression scale and Nottingham Extended Activities of Daily Living were used. A summary of the assessment schedule is shown in Table 1.

Measures were chosen, which were reliable, valid, and easy for participants to complete, thus minimising participant burden. The intention was to capture information about impairments and functional limitations that Brain-in-Hand could potentially support, as its use in acquired brain injury was largely unknown prior to the study. The Nottingham Extended Activities of Daily Living was chosen because it indicates competence with activities of daily living and was short, thus limiting participant burden. At least two goals relevant to each participant were set at baseline using Goal Attainment Scaling.<sup>23</sup> Potential goals were discussed with the participant's treating occupational therapist (if applicable) prior to, or during the baseline session to ensure goals were relevant and attainable. Goals were then identified by the participant and discussed with the researcher (JK). Patient-stated goals were recorded and converted into SMART (Specific, Measurable, Achievable, Realistic, Time-bound) goals. Where necessary, the researcher (JK) contacted the treating therapist to clarify the patient goals. Goals were reviewed for attainment at 6 and 12 months post-intervention. This method was chosen as goals could be weighted to reflect importance, and attainment scores calculated across the study period using a spreadsheet.<sup>23</sup>

Semi-structured interviews were conducted with participants with acquired brain injury and healthcare workers at 6 months since beginning to use Brain-in-Hand. Data were collected on acceptability of Brain-in-Hand, and barriers and facilitators to use. Interviews were audio recorded and transcribed. Example interviews questions are shown in Appendix 1.

Participants with acquired brain injury received the Brain-in-Hand app at 6 weeks post-baseline. They were

		_	2	З	I	4	5	6	7	8
Measure	impairment assessed	Baseline	Week 2	Week 4	ntion (d	Week 8	Week 10	Week 12	6 months	12 months
HADS	Anxiety and depression	>	>	>		>	>	>	>	>
NEADL	Independence	>	>	>	tni 9₩	>	>	>	>	>
MSNQ	Cognition	>							>	>
CIQ	Participation	>							>	>
GAS-Light	Goal attainment	>							>	>
FAS	Fatigue	>			riari ntri				>	>
EuroQol-5D-5 L	Quality of life	>							>	>
HADS: Hospital anxiet	HADS: Hospital anxiety and depression scale: Northinsham extended activities of daily living: MSNO: Multiple sclerosis neuropsychological screening questionnaire: CIO: Community interration	Vottingham exte	inded activities o	of daily living: MS	SNO: Multiple	sclerosis neuro	posvchological scre	sening au	estionna	estionnaire: CIO: Commu

Assessment number

Table I. Assessment schedule.

ADS: Hospital anxiety and depression scale; NEADL: Nottingham extended activities of daily living; MSNQ: Multiple sclerosis neuropsychological screening questionnaire; CIQ: Community integrati	Jestionnaire; GAS: Goal attainment scaling; FAS: Fatigue assessment scale; EQ-5D-5 L: EuroQol 5-dimensions 5-levels.
HADS: Ho	questionnai

offered a 2-hour training session. They were instructed to use it for 12 months. The TIDieR checklist<sup>24</sup> was used to describe the intervention components, process and delivery (see Table 2). The intervention was fully personalisable; each participant set specific goals and tailored Brain-in-Hand to their needs. Participants were given a workbook to complete 2 weeks prior to the set-up session, which encouraged them to think about goals and the types of daily reminders they would like to receive. During the set-up/ training session, Brain-in-Hand was programmed for use by the researcher, and the intervention commenced immediately. All participants received a Brain-in-Hand license and used their existing smartphone, which enabled them to download and login to the app, and access an online portal. Each user was provided with a login name and asked to set their own memorable password. Training was provided by a researcher (author JK), who was trained on how to deliver this session by the Brain-in-Hand company. A 2-h training session was offered to each participant, during which a training manual was used to guide the set-up, along with using the completed participant workbook. The training manual also acted as a 'how to' guide for the participants, providing instructions for making changes to the app. Individuals were shown how to use the app functions. Individuals were able to personalise their Brain-in-Hand diaries by adding daily events (such as taking medication) and changed the traffic light function to suit their specific needs (e.g. fatigue or anxiety). Users were able to tailor the traffic light labels so they were relevant to them (e.g. high fatigue (red) could state 'I really need to sleep, I feel exhausted') (see Figure 1). Each participant was asked to choose a "mentor" (typically family member, partner or carer) to provide support, monitor traffic lights and had access to the online portal during the study. The Brain-in-Hand company provided technical support where necessary, however the trainer (author JK) often was the first point of contact for troubleshooting.

Quantitative data were analysed to present the perceived change in mood, functional independence, fatigue, cognition, quality of life, goal attainment and participation for participants with acquired brain injury measured using questionnaires. The suggested clinical cut-off scores were identified from published sources.<sup>25–27</sup> Difference in scores for individual cases, mean averages across cases and mean differences were statistically analysed. For parametric tests, mean averages and standard deviations were presented for comparison between the questionnaire measures with associated p values. Overall response rates and completeness of questionnaires returned were assessed. All analyses were completed on IBM SPSS version 22.0 and GraphPad Prism version 6.0.

Interview data were analysed thematically using the Framework approach<sup>28</sup> to elucidate factors influencing the effectiveness of Brain-in-Hand and the barriers and facilitators

to its use, and acceptability. The coding matrix was informed by the Behaviour Change Wheel<sup>29</sup> and International Classification of Functioning, Disability and Health (Figure 2).<sup>30</sup>

The International Classification of Functioning, Disability and Health was chosen for its focus on functioning and disability, and personal and environmental contextual factors (Figure 2), which are important to understand the use and acceptability of a smartphone app like Brain-in-Hand. Each component can interact with another component in two directions, meaning that any intervention affecting one area can potentially affect outcomes in another. The International Classification of Functioning, Disability and Health provides a common language for reporting the qualitative findings. In the context of acquired brain injury, it has facilitated the identification of barriers and facilitators of interventions and enabled the exploration of effect on functional states (impairments, limitations, and restrictions). The Behaviour Change Wheel suggests that behaviour change is dependent on three components: capability, opportunity, and motivation. As Brain-in-Hand is intended to influence behaviour change, the Behaviour Change Wheel seemed a logical choice for the interview topic guide. It was also used successfully to identify barriers and enablers to Brain-in-Hand use in a previous study.<sup>31</sup>

Interview transcripts were coded independently by two authors (JK and AW). Data were analysed using NVivo (QSR International Pty Ltd). Codes were compared and collated into themes. Findings were triangulated with the authors, people with acquired brain injury, and healthcare workers to enhance validity of findings.

A convergence coding matrix<sup>32</sup> was used to synthesise and integrate the quantitative and qualitative data. Themes across both datasets were searched for agreement and disagreement between the two methods. The synthesised data were coded according to their complementarity, disagreement or silence.

#### Results

A total of 14 people were recruited to the study, 10 were adults with acquired brain injury and three healthcare workers (two occupational therapists and one support worker) (Figure 3). A summary of the acquired brain injury participants' characteristics is shown in Table 3.

#### Quantitative findings

A summary of outcome measures combined across all cases is shown in Table 4. Participants set various goals at baseline, which was discussed with their treating therapist and/or family member; examples of participant goals are shown in Table 5. Goals were similar across cases (although specifically tailored to individual circumstances) and categorised under: independence, self-management, fatigue, mood, physical, memory, or other.

Criteria	TIDieR Definition	Description
Brief name	Name or phrase to describe the intervention	Brain-in-Hand: personal smart technology designed to improve independence and self-management
Why?	Rationale behind the intervention, goal or theoretical basis	• Brain-in-Hand was specifically engineered to support the management of persistent emotional and behavioural problems in the autistic population, which are also commonly seen in people with traumatic brain injury or stroke
		<ul> <li>It has not been systematically evaluated in the acquired brain injury population</li> <li>Research to demonstrate the effectiveness of brain-in-hand in acquired brain injury is timely, as technology currently</li> </ul>
What materials?	What was provided to the participant either before receiving the intervention or while it is being delivered	<ul> <li>available to support patient rehabilitation is limited</li> <li>Participants were provided with a workbook 2 weeks prior to receiving the intervention and told to complete prior to their training/set-up session</li> <li>All participants received a Brain-in-Hand license and used their existing smartphone, which enabled them to download and login to the app, and access the online portal In most cases, they had a laptop or computer so that they could edit their diary online, via the portal. However, this could also be accessed via a smartphone internet browsee</li> <li>Participants were provided with a training book during their</li> </ul>
		set-up training session, which provided instructions for adding diary entries to the app and explained the functions of Brain-in-Hand. This was used during the session and lef with the participant
What procedures?	What were the processes involved in using the intervention, describe any supporting activities that were implemented	<ul> <li>A 2 h training session was offered to each participant. Individuals were shown how to use the different functions of Brain-in-Hand by the researchers and this was done in a systematic way using a checklist, which included: overview of the system, adding a diary entry, changing dates, frequency and times of events, duplicating a diary entry, adding unplanned events, how to use the traffic lights and downloading the app</li> <li>Once the researcher had covered each training section,</li> </ul>
		<ul> <li>participants were asked if they needed anything repeating</li> <li>Following this, each acquired brain injury participant was asked to demonstrate adding a diary entry, pressing a traffic light, updating the app and general navigation of the system before the researcher was confident they could competently use Brain-in-Hand</li> </ul>
		<ul> <li>During the final part of the session, the researcher helped individuals personalise their Brain-in-Hand diaries by adding daily events (such as taking medication) and changed the traffic light labels to suit their specific needs/goals (i.e., monitoring fatigue or anxiety)</li> <li>The researcher referred to the workbook that had previously been given to the participants and guided the set.</li> </ul>
		up of the system, if it had been completed. If this had no been completed, the researcher used the workbook as a prompt to discuss goals the individuals might want to achieve and think about their daily routine. The researche allowed the participant to take control at this point and navigate the system, helping where necessary

Table 2. TIDieR description of Brain-in-Hand (BiH) intervention.

(continued)

Table 2. (continued)

Criteria	TIDieR Definition	Description
Who provided?	For each person that was involved in providing or delivering the intervention	<ul> <li>PhD student trained to use Brain-in-Hand over a two day period (approximately 8 h)</li> <li>If applicable, their therapist attended the set up session or they advised on relevant goals</li> </ul>
		<ul> <li>Mentor attended set up session if one was nominated by the participant</li> </ul>
How?	Describe how the intervention was delivered or provided	• The intervention was set up face-to-face, but following this initial session, the app was intended for use by the individual in their daily life at home
		<ul> <li>The intervention was ongoing and used by the participant in their own environment</li> </ul>
Where?	Where was the intervention delivered?	<ul> <li>Brain-in-Hand was set up face-to-face with every participant</li> <li>This was either in their home or in a hospital setting, depending on their preference</li> </ul>
When and how much?	Amount of time the intervention was delivered for and frequency	<ul> <li>Participants received two hours training. During this session, the app was set-up and various events, problems and solutions added to the diary</li> </ul>
		<ul> <li>The participants were provided with Brain-in-Hand to use for 12 months</li> </ul>
		<ul> <li>At 6 months post-intervention, participants were interviewed and at this point any issues with Brain-in-Hand could be addressed. For all participants, suggested changes were taken on board and problems resolved if possible</li> </ul>
Tailoring	Describe if the intervention was personalised, how, when and why	<ul> <li>Brain-in-Hand was personalised for each participant depending on their specific needs</li> <li>Diary entries could be entered as appropriate for the participant and reminders could be set for any task. The problems/solutions could be completely tailored to the</li> </ul>
		<ul> <li>individual by entering any text</li> <li>The traffic light system was able to monitor anxiety or fatigue. The participant decided at the set-up session which symptom they would prefer to monitor</li> </ul>
		<ul> <li>The text beside the traffic lights could be fully personalised so it was relevant to the individual and facilitated their decision when reporting anxiety/fatigue levels (i.e., were they feeling green, amber or red).</li> </ul>
		<ul> <li>The diary, reminders and app settings (except traffic light settings) could be changed at any point throughout the study</li> </ul>
Modifications	Describe if the intervention was modified in any way, how, when and why	<ul> <li>The app was updated during the study and the appearance changed to make it more visually appealing, however the layout was similar and participants did not require any further training</li> </ul>
How well?	Describe if intervention fidelity and adherence was assessed	<ul> <li>Intervention fidelity was not assessed as this was a small series of case studies. However, the researcher providing the training to participants used a checklist during each session to ensure the same points were covered and all users received the same information</li> </ul>
		<ul> <li>Participants received up to 2 h training and competency was assessed. They were also provided with a workbook two weeks prior to receiving Brain-in-Hand and given a training manual during the set-up session</li> </ul>

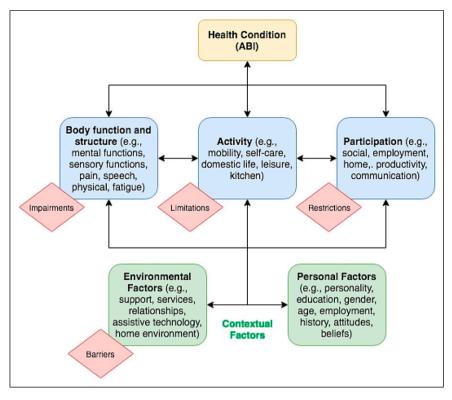


Figure 2. Summary of International Classification of Functioning, Disability and Health (ICF) components for acquired brain injury (ABI).

Participants Goal Attainment Scale scores increased significantly between baseline (mean = 37.21, SD = 0.76) and 6 months (mean = 53.9, SD = 11.02); t(7) = 4.20, p = 0.004) (Figure 4, Table 4). Although there were no significant changes in any other outcome measures, there was a mean decrease in Multiple Sclerosis Neuropsychological Screening Questionnaire scores between six months and 12 months postintervention (mean change = -3.75, SD = 8.50, CI -10.85to 3.35).

Some negative scores were reported, including a mean decrease in Community Integration Questionnaire scores between baseline and 6 months (mean change = -3.38, SD = 7.23, CI –9.42 to 2.67), indicating an initial reduction in participation. There was also a mean decrease in Not-tingham Extended Activities of Daily Living scores between baseline and 6 months (mean change = -0.75, SD = 3.66, CI –3.81 to 2.31).

## Qualitative findings

An overarching theme of context was identified as a key influencer of Brain-in-Hand use and effectiveness. We define context as an individual's situation, or factors involving the person and the surrounding environment.<sup>30</sup> Within this, four main themes were identified. Having appropriate support (set up, monitoring and goal identification/revision), motivation and self-awareness appeared to facilitate Brain-in-Hand use.

Insight and self-awareness. Insight emerged as a common theme running through the interviews. Analysis highlighted the need for people with acquired brain injury to have a level of self-awareness for Brain-in-Hand to be useful. Individuals who have some insight and self-awareness are often more able to self-monitor and self-correct behaviour. Participants who had insight into their limitations tended to have more realistic expectations of Brain-in-Hand and how it could help them. They were also more aware of when they needed to change behaviours and amend goals, or use the app to change their routine (e.g. taking more rests in the day to manage fatigue). After using Brain-in-Hand for 6 months, one participant became more aware of his anxiety and recognised that he needed to manage this better. By using the app, this person appeared to gain greater insight into when he became anxious and developed ways to control these feelings:

Yeah, it's [using the Brain-in-Hand traffic lights] made me face up to that I have got like an anxiety problem because it's not linked to any kind of depression or anything like that... yeah and this [Brain-in-Hand] reminds me all day that I need to be mindful. (Participant 5, male, traumatic brain injury)



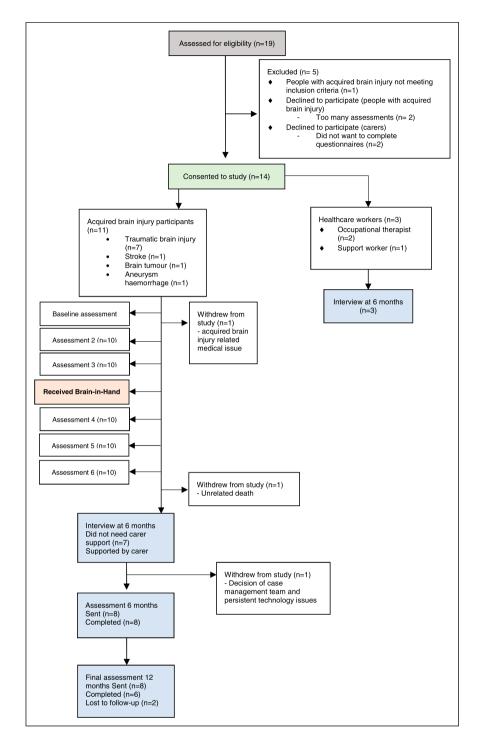


Figure 3. Recruitment diagram.

However, one therapist suggested that even when individuals have a level of insight, they might not know when to press the appropriate traffic light. Some acquired brain injury users might struggle to recognise symptoms of fatigue or anxiety, which makes it difficult to monitor when these 'red' episodes (i.e. highly fatigued/anxious) appeared most frequently. The occupational therapist mentioned that one barrier to Brain-in-Hand use and its effectiveness and might be users' inability to recognise or acknowledge their symptoms:

						HADS anxiety <sup>t</sup>	٩٨	HADS depression <sup>b</sup>	ssion <sup>b</sup>	NEADL <sup>a</sup>					
<u>(</u>			:		Rehabilitation	-	Rasch	-	Rasch	-	Rasch	EQ5D-5L	0	(	
Case ID	Gender	Gender Age (years) Injury	Injury	Time since injury	at baseline	Standard	converted	Standard	converted	Standard	converted	Index"	CIQ	MSNQ	FAS
_	Male	32	TBI	3-4 years	от	0	0	_	0	63	51	00.1	25	22	=
2	Male	48	Brain tumour surgery	18–24 months	٩N	2	_	2	2	65	53	0.84	27	32	21
m	Female	24	TBI	I 2–I 8 months	OT, PT, SLT	12	01	6	5	37	27	0.59	8	33	32
4	Male	48	TBI	Over 4 years	OT, NP	6	8	6	5	58	46	0.66	15	40	27
5	Male	38	TBI	I 2–I 8 months	OT, NP	81	16	0	7	62	52	0.55	=	48	32
6	Male	50	TBI	18–24 months	от	16	16	15	01	39	31	0.32	=	59	41
7	Male	32	TBI	12–18 months	от	5	4	٣	2	57	47	0.84	17	30	20
8	Male	58	Hypoxia	12–18 months	от	6	5	7	5	37	32	0.65	4	39	33
6	Female	52	Aneurysm	I 2–I 8 months	٩N	41	13	4	8	49	37	0.71	17	47	42
			haemorrhage												
01	Male	66	Stroke	Over 4 years	PT, SLT	2	2	2	_	39	28	0.73	01	23	17
=	Male	30	TBI	18–24 months	от, рт	17	*	7	×	46	*	0.26	15	49	UZ
Mean (SD)	Ι	43.45	Ι	I	I	9.18 (6.57)	7.5 (6.04)	6.91 (4.78)	4.5 (3.24)	50.2 (11.2)	40.4 (10.5)	0.65 (0.22)	15.5 (5.97)	38.4 (11.6)	27.6 (10.2)
		(13.15)													
95% CI	Ι	34.62-52.29	Ι	I	I	4.77–I 3.6	3.18-11.82	3.70-10.12	2.18-6.82	42.68–57.69	32.92-47.88	0.50-0.80	11.44-19.47	30.55-46.18 20.27-34.93	20.27-34.93
Score	Ι	24-66	Ι	I	Ι	0-18	0-16	I–I5	0-10	37–65	31-53	0.26-1.00	8–27	22–59	11-42
range															
alotte	i en														
blower s	core ind	icates a neg	blower score indicates a negative outcome.												
		Anvioty and	DOVEL SOLE INDUCES A POSITION CONCUMPTION FOR A Artivities of Daily Living EO. 51. EuroO. 15. Aimonoisone 5. Jourle: "OO: Community Internation Outerionics" MSND DADE: Sole Induces a positive and Domension Scale. NEAD1 - Noteinaham Extended Artivities of Daily Living EO. 51		Juham Extensi	Hod Activitie	se of Daily Liv	ing EO EO		5 -dimension:	e E-lovale: CIC	. Community	Integration	Outortion	CINIO.
	Sclerosis	Neuropsyc	Multiple Scierosis Neuropsychological Screening Questionnaire;	Questionnaire	: GAS: Goal	Attainment	Scaling; FAS: I	ratigue Asses	ssment Scale;	SU: standard	deviation; O	GAS: Goal Attainment Scaling; FAS: Fatigue Assessment Scale; SU: standard deviation; O I: Occupational therapist; NM: Neuropsychologist;	al therapist; l	NP: Neurop	sychologist;

Table 3. Summary of acquired brain injury participant characteristics.

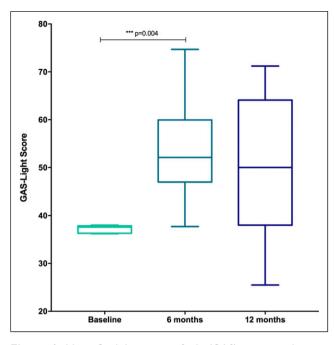
Multiple Sclerosis Neuropsychological Screening Questionnaire; GAS: Goal Attainment Scaling: FAS: Fatigue Assessment Scale; SU: standard deviation; PT: Physiotherapist; SLT: Speech and language therapist; NC: Not completed. Red coloured numbers indicate probable clinical impairment/presence of the outcome in question (i.e., anxiety, depression, cognitive impairment).

	-					-		
						Mean change (SD, 95% CI)		
		Mean	SD	Min	Мах	Baseline-6 months	6–12 months	Baseline-12 months
HADS anxiety <sup>b</sup>	Baseline	7.50	6.04	0	16	0.38	-0.33	0.83
	6 months	8.25	5.82	_	16	(SD = 1.77, CI - 1.10  to  1.85)	(SD = 1.63, CI - 1.38  to  2.05)	(SD = 1.47, CI - 0.71  to  2.38)
	12 months	7.83	6.85	_	8			
HADS depression <sup>b</sup>	Baseline	4.50	3.24	0	0	0.75	-0.5	0.17
	6 months	5.50	3.78	_	12	(SD = 1.91, CI - 0.85  to  2.35)	(SD = 1.98, CI - 2.57  to  1.57)	(SD = 2.14, CI - 2.08  to  2.41)
	12 months	4.50	2.35	_	8			
<b>NEADL<sup>a</sup></b>	Baseline	40.40	10.46	27	53	-0.75	-0.5	-0.167
	6 months	35.38	13.91	61	54	(SD = 3.66, CI - 3.81  to  2.31)	(SD = 4.18, CI - 3.89  to  4.89)	(SD = 6.43, CI - 6.92  to  6.58)
	12 months	34.67	18.52	4	55			
GAS-Light <sup>a</sup>	Baseline	37.21	0.76	36.2	38	16.56	-3.3	12.77
1	6 months	53.9	11.02	37.7	74.4	(SD = 11.15, CI 7.24–25.88)	(SD = 17.67, CI - 19.64  to  13.04) $(SD = 16.99, CI - 2.94  to  28.49)$	(SD = 16.99, CI - 2.94  to  28.49)
	12 months	50.01	16.68	25.5	71.2	$^{***}(p = 0.004)$		
CIQ	Baseline	15.50	6.29	8	27	-3.38	0.5	3.17
	6 months	14.63	4.37	0	21	(SD = 7.23, CI - 9.42  to  2.67)	(SD = 5.47, CI - 5.34  to  6.24)	(SD = 9.33, CI - 12.95  to  6.62)
	12 months	16.17	6.11	9	23			
<b>MSNQ</b>	Baseline	37.30	11.68	22	59	-3.75	-2	-2.5
	6 months	34.13	16.11	8	55	(SD = 8.50, CI - 10.85  to  3.35)	(SD = 3.16, CI - 1.32  to  5.32)	(SD = 10.82, CI - 13.86  to  8.86)
	12 months	33.50	12.91	22	57			
FAS <sup>b</sup>	Baseline	27.60	10.24	=	42	-1.25	2	1.67
	6 months	27.38	60.6	=	6	(SD = 4.59, CI - 5.09  to  2.59)	(SD = 4.05, CI - 2.25  to  6.25)	(SD = 5.28, CI - 3.87  to  7.21)
	I2 months	29.00	10.22	16	42			
EQ-5D-5 L <sup>a</sup>	Baseline	0.69	0.19	0.32	_	0.055	-0.11	-0.057
	6 months	0.73	0.20	0.46	_	(SD = 0.098, CI - 0.027  to  0.14) $(SD = 0.19, CI - 0.31  to  0.09)$	(SD = 0.19, CI - 0.31 to 0.09)	(SD = 0.15, CI - 0.22  to  0.10)
	12 months	0.64	0.34	-0.016	0.906			
<sup>a</sup> measures where a higher score indicates a positive outcome. <sup>b</sup> measures where a lower score indicates a positive outcome.	her score indicater score indicater	ites a positiv tes a positiv	ve outcomé 'e outcome	di ci				
HADS: Hospital Anxiet	y and Depressio	in Scale; NE	ADL: Notti	ingham Exte	nded Activ	ties of Daily Living; EQ-5D-5L: EuroQo	HADS: Hospital Anxiety and Depression Scales, NEADL: Nottingham Extended Activities of Daily Living, EQ-5D-5L: EuroQol 5-dimensions 5-levels; ClQ: Community Integration Questionnaire; MSNQ:	nity Integration Questionnaire; MSNQ:
rutupe scierosis Neuropsycr difference in scores ( $p < .05$ ).	opsycnological : < .05).	ocreening 🗸	uestionnair	e: CAN: CO	al Attainme	nt ocalling; FAO: Faugue Assessment oca		ce intervais. Theired t-test, significant

Table 4. Summary of quantitative data collected at baseline, 6 and 12 months post-intervention.

Goal category	Patient stated goal	SMART goal	Goal attainment
Independence self- management	Live independently with minimal support in new apartment and manage household tasks with little help from parents	To self-manage in new home with minimal help and complete all necessary household tasks and food shopping, using Brain-in-Hand diary to provide this structure. To complete at least 70% all tasks over 6 months measured by Brain-in- Hand app	(+2) Yes – better than expected Completed 73.5% tasks added to Brain-in-Hand diary (data exported from Brain-in-Hand app)
Fatigue	Manage fatigue better	Rest more during the week and complete at least 60% of Brain-in- Hand 'rest' tasks. Use traffic lights every day to monitor fatigue levels	<ul> <li>(-1) No – partially achieved</li> <li>Over the 12 months, only completed</li> <li>29.5% 'rest' tasks, however, did use</li> <li>the traffic lights to monitor fatigue</li> <li>levels for the majority of the study</li> </ul>
Independence mood	Return to work and manage anxiety when at work	Return to work and use Brain-in-Hand to monitor his anxiety levels when at work. The traffic lights should be used daily to help them recognise patterns of anxiety and use solutions to manage this. Brain-in- Hand should be used as a supportive tool at work and discussed with employer	<ul> <li>(0) Yes – expected. Returned to work within 6 months of receiving Brain- in-Hand</li> <li>Using Brain-in-Hand at work to monitor anxiety levels and employer happy for them to take time out if feel anxious. Successfully using Brain-in-Hand as a supportive tool when working, finds it very useful and an 'excuse' to leave if need space</li> </ul>
Independence memory	Take control of daily routine and remember appointments	Be more independent and rely less on support workers by adding all appointments and important daily tasks to Brain-in-Hand diary. Goal to complete at least 60% of all tasks on Brain-in-Hand diary	•
Physical memory	Do therapy exercises more often	Complete therapy exercises, specifically speech therapy exercises each day. Reminders to do these tasks were added to his Brain-in-Hand diary. Goal was to complete at least 60% of 'exercises' tasks on Brain-in-Hand diary	<ul> <li>(-1) No – no change</li> <li>Only completed 40.1% of 'exercise' tasks in the first 6 months</li> </ul>
Mood self- management	Manage anxiety better using breathing exercises or going for a walk	Use Brain-in-Hand to remind them to	(0) Yes – as expected. Using Brain-in- Hand to remind them to take walks each day to help with anxiety. Also using the solutions on the app to help with breathing exercises, but was not clicking on the solutions
Self-management physical	Carry out daily activities without having to be reminded, such as therapy exercises	To use Brain-in-Hand diary to set exercise reminders and complete them without having to be asked. The goal was to complete at least 50% 'exercise' tasks over the 12 months	(+2) Yes – better than expected Completed 53.2% of exercise tasks during the 12 months

Table 5. Example goals set using Goal Attainment Scaling (GAS).



**Figure 4.** Mean Goal Attainment Scale (GAS) scores with interquartile range and range at baseline, 6 months and 12 months post-intervention.

I think for our patients, I think they're trying desperately not to press that for 'I'm struggling', we wanted them to press it [Brain-in-Hand traffic lights] for fatigue, but again you've still got an insight issue for am I fatigued or do I want to press this button. Erm they're trying to prove to themselves that they can cope, they don't want to press the button [red traffic light]. (Participant 11, occupational therapist)

Some individuals may have found it hard being honest with themselves when rating their fatigue/anxiety levels and accepting that they have a problem.

Support and training. Interviews revealed that ongoing support and training would be beneficial for Brain-in-Hand users. Training for healthcare workers was highlighted by occupational therapists as an important facilitator to provide them with the knowledge and explore potential uses of Brain-in-Hand for supporting their patients. Appropriate support was also a key facilitator to the effective use of the intervention. One participant chose his wife as his Brain-in-Hand 'mentor'. Although initially useful for selfmonitoring, the participant admitted he was not honest when monitoring his fatigue levels as the study progressed. This meant that he was not using the traffic lights appropriately and therefore not benefiting from this component of the app:

I don't want to let Kim know that I am struggling, but Kim doesn't really see that I am struggling erm and as she's my wife

more than anything else I don't want to let her think I am struggling too much because she will probably dump me...so there is a fear of upsetting... maybe it should be somebody else other than Kim so I get support from another angle without Kim needing to be worried. (Participant 2, male, acquired brain injury)

Participants highlighted the need for frequent contact with the Brain-in-Hand support team (based within the company) to ensure the app was working correctly and to prompt them to think about things they were struggling with (e.g. diary entries). Linking back to the theme of insight, some people may not have the self-awareness to ask for help when the app is not working. This was identified as an issue for a number of participants; several did not ask for help when they needed it. One participant forgot her password that was set during the initial training session and failed to request support. As a result, she did not use Brain-in-Hand for several weeks.

Motivation to use the app and change behaviours. Many participants admitted to lacking motivation and some recognised that this affected their use of Brain-in-Hand. Reduced motivation impacted on the effectiveness of Brain-in-Hand and goal attainment. Some individuals were motivated to maintain Brain-in-Hand use, as they were achieving goals and could see the benefits. One person said the app was like having a friend, which motivated him to use it, as it was an opportunity to think about how he was feeling:

Well at the start it was a bit of a friend really, erm and yeah it was nice to have it pop up on my phone how are you feeling because it was making me think how I was feeling at the time. (Participant 5, male, traumatic brain injury)

The impact of reduced motivation was evident for some individuals who did not frequently use the traffic light system and lost interest over the 12-months intervention period. There was also a connection between unachieved goals and demotivation.

Technology. Participants identified a number of barriers to use and potential improvements for Brain-in-Hand, which might facilitate its use in the acquired brain injury population. Most participants mentioned that being able to edit the app on the smartphone or smart device would improve accessibility. The current system only allowed users to update reminders on the online portal rather than their phone - which was a barrier to those with memory impairment who needed to be able to access the diary 'onthe-go'. Others felt that the reminders needed follow-up notifications to ensure they had completed a task. One participant who was using the app to manage fatigue, spoke about reminders for rests. That's the other thing as well, when you, when it says rest, you complete it, but you, you're pressing rest you've completed your rest before you have your rest. So then if something comes up and stops you from having the rest when you've had your reminder to have your rest, say like a phone call comes through or a client phones you up, then you've failed to have your rest. (Participant 2, male, acquired brain injury)

One participant struggled to act on instructions he received by phone. His support worker had noticed that the phone reminders did not work for this person who needed direct instructions:

But if it's like a reminder that's not, it's not a direct instruction, it doesn't seem to have the same effect, like James said he'll think 'oh, I'll do that in 10 min' and then he's forgotten, erm which brings me onto my next bit that it needs to follow that up. (Participant 13, female, support worker)

The support worker also discussed the need for followup reminders on the app to check that users had actually completed a task. Other participants discussed the need for tasks to have a start and finish, especially if tasks were related to activities that could be completed immediately. Users found the traffic light monitoring system to be the most useful part of Brain-in-Hand, although a few people preferred the reminder function.

#### Data convergence

The quantitative and interview data were generally complementary, but did not agree on all themes (Table 6). Although the quantitative data alone suggested some improvement in various outcome measures, such as cognition, fatigue, independence and a significant increase in goal attainment over 6 months, the qualitative data provided an important additional perspective on the findings of this study, highlighting potential improvements not detected by the outcome measures.

The outcome measures did not capture all of the potential benefits of Brain-in-Hand that were mentioned in participant interviews. The data were discrepant on one aspect – anxiety. The quantitative data showed no improvement in mood (measured using the Hospital Anxiety and Depression scale) across participants, however some individuals qualitatively reported the benefit of using Brain-in-Hand for anxiety management, suggesting that the app (specifically the traffic light monitoring system), was improving anxiety levels. Quantitative measures of independence/functional outcomes did not significantly improve across participants, however for six individuals, the Nottingham Extended Activities of Daily Living score did increase. This complemented the qualitative data, finding that some participants felt empowered after using Brain-in-Hand and other felt they had regained independence by prompting them to complete daily tasks, such as taking their medication and doing therapy exercises.

In addition, the converged data suggested that support was important to all participants, in terms of motivation, but also ensuring they could troubleshoot any technical issues. After the 6 months interview, contact from the researcher became less frequent and support was effectively withdrawn (even though participants were encouraged to contact the research team at any time). At this point, Brain-in-Hand usage dropped and task completion decreased, suggesting that ongoing support was important to encourage participant use. The change in usage is shown in Figure 5. The qualitative data supported this, as participants consistently highlighted the need for support, to help with technology problems, motivate them to continue using the app, and talk them through updating their diary, reminders and solutions.

## Discussion

The data obtained from each participant provided valuable information about the potential uses of Brain-in-Hand for individuals with acquired brain injury and identified technological improvements necessary for implementation in this population. Overall, Brain-in-Hand helped participants set and achieve goals and, in some cases, facilitated selfmanagement.

Personal and environmental (contextual) factors, such as insight and self-awareness, relationships, environment, support and services, determined the extent of use, and need to be considered when implementing Brain-in-Hand, or similar interventions. Context, plays a pivotal role in the effectiveness and long-term use of Brain-in-Hand. It is clear that such contextual factors (insight, ongoing support, training, motivation, technology) need to be considered and appropriate for the acquired brain injury user, if Brain-in-Hand is to work in this population; an idea which was reflected throughout the interviews. This is something that should be considered when implementing smart technologies and the infrastructure surrounding the use of such technologies (i.e. the context in which it will be delivered) needs to be better understood before they can be effectively implemented.

Although a lack of engagement and motivation are common issues when implementing smart technologies like Brain-in-Hand, it appeared that additional support and selfawareness may improve compliance in the acquired brain injury population. Unrealistic goals and lack of motivation can result from impaired self-awareness or lack of insight,<sup>33</sup> which means that this group of individuals could benefit from additional support when setting goals and using such technologies. This highlights the need for training in goal setting for those involved in setting up the app for use, or the

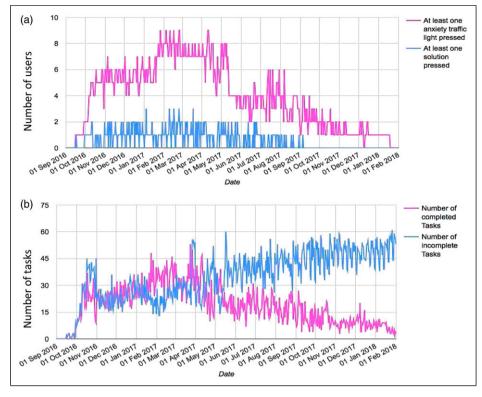
Theme/key finding	Quantitative findings	Qualitative findings	Convergence coding
Anxiety	There were no obvious changes in the anxiety scores (HADS questionnaire) for any of the participants, suggesting that Brain- in-Hand was not having any effect on this outcome	Out of those participants monitoring anxiety, one of them reported a clear improvement in his anxious demeanour after using Brain-in- Hand for 6 months. He was using the traffic lights to monitor his anxiety levels and managing them better, especially when at work. He was also using the problems and solutions to cope when he was feel anxious. This suggests that Brain-in- Hand was having a positive effect on his anxiety levels	Disagreement – the qualitative findings suggest that Brain-in-Hand was helping one of the participants with high anxiety, however this was not observed in the quantitative data
Cognition	There was no significant improvement in cognitive function, however the combined data showed a mean decrease in MSNQ at 6 months and again at 12 months. This suggests Brain-in- Hand was having a positive effect on cognitive function	Participants stated that Brain-in-Hand	Complementarity The findings both suggest that Brain- in-Hand was useful to remind participants to complete important tasks
Contextual factors	There were no specific measures indicating the importance of context in supporting the set up and use of BiH	Interview findings revealed contextual factors as an overarching theme. All participants suggested at least one barrier/facilitator linking to environmental and personal factors. Context was mentioned by HCPs as something that has to be right for an intervention to work. Context was pivotal to the use and effectiveness of Brain-in-Hand	Silence – only the qualitative data identified contextual factors as an important finding
Fatigue	Some participants recorded an improvement in fatigue (FAS score) at 6 months post- intervention, others improved at 12 months post-intervention. However, some participants that were monitoring fatigue with the traffic lights did not report a decrease in fatigue, and some experienced more	Fatigue was mentioned by some participants who stated that Brain- in-Hand was helping them self- monitor using the traffic light system	Complementarity
Functional outcomes/ independence	Six participants improved on their NEADL score at 6 months post- intervention and four improved at 12 months post-intervention. This suggests that Brain-in-Hand was facilitating self-management	Some participants stated that they felt more independent and empowered after using Brain-in-Hand. Others felt that it had helped them self- manage and rely less on others to remind them to complete tasks	Complementarity

## Table 6. Convergence coding matrix.

(continued)

Theme/key finding	Quantitative findings	Qualitative findings	Convergence coding
Goal attainment	Brain-in-Hand appeared to have a positive effect on goal attainment for the majority of participants. Seven of the eight participants achieved at least one Brain-in- Hand related goal at 6 or 12 months post-intervention, two of these achieved 3 of their goals. There was also a significant increase in overall goal attainment (p = .004) between baseline and 6 months post-intervention	Participants stated that Brain-in-Hand had helped them work towards specific goals	Complementarity
Insight	There was a clear drop in NEADL scores from baseline to 2 weeks post-baseline for 8 of the 10 participants. This suggests a lack of insight regarding their abilities with everyday tasks and how much support they needed. As the study progressed, it became clear that those who lacked insight did not use Brain-in-Hand as much, as they could not see a use for it	Lack of insight was a key barrier to Brain-in-Hand use and effectiveness. Participants that had a level of insight prior to receiving Brain-in-Hand, or developed it as a result of using the intervention, stated that they had benefitted more	Complementarity Data sets do not completely agree but share complementary information about the participants lacking insight
Motivation		Motivation was a key theme identified by nearly all participants. Those that had motivation to use Brain-in- Hand benefitted more from it and achieved more goals. Some that were not motivated recognised this and planned to use it more in the final 6 months	Silence – only the qualitative data identified motivation as a key findings
Ongoing support	As support was withdrawn, the number of completed tasks decreased and incomplete tasks increased. This happened shortly after the 6 months interviews	Mentioned by most participants that ongoing support would have been useful to encourage them to continue using Brain-in-Hand and help them update their diary, even though they found it easy to use	Complementarity and convergence
Self-monitoring	Traffic light usage for all participants over the study period was consistent, suggesting that people were using it for self-monitoring. Out of the 6 participants monitoring fatigue, 4 of them had reported a decreased FAS score at 6 months post-intervention. One participant initially increased in FAS score at 6 months, but then decreased below baseline score at 12 months post-intervention. Out of the 4 participants monitoring anxiety, 2 improved (decreased HADS anxiety score) at 12 months. One of these used the traffic lights consistently to monitor his anxiety levels		Complementarity

## Table 6. (continued)



**Figure 5.** Data exported from the Brain-in-Hand app showing the change in usage over time. Data presented from September 2016 (first case received intervention) to February 2018 (final case end of study). Support and frequent contact from research team reduced around 6 months (April 2017).

Graph A: total number of users at a certain period of time that pressed at least one traffic light (monitoring fatigue or anxiety) shown in pink and those pressing at least one solution shown in blue; Graph B: total number of users at a certain time period that completed tasks on their BiH app shown in pink and total number of users that did not complete tasks shown in blue.

need for involvement of the therapy team, where rehabilitation is ongoing.

Convergence coding facilitated the synthesis of quantitative and qualitative findings, and offered greater insights into the data than individual analysis.<sup>34,35</sup> Where data did not completely converge, it offered complementary information about the key themes and provided context to the quantitative outcomes. As there was no clear change on most quantitative measures (other than a significant increase in goal attainment), it appeared that Brain-in-Hand had been largely ineffective. However, convergence of data highlighted potential reasons for poorer outcomes, such as the impact of life changes (e.g. relationship breakdown, general lack of motivation), which were not specifically linked to Brain-in-Hand.

The convergence of data also emphasised environmental (e.g. support, training) and personal barriers (e.g. insight, motivation), that need to be addressed prior to implementation of Brain-in-Hand in a healthcare setting. Barriers included appropriate support in terms of technological troubleshooting, but also support for the individual to help with goal setting and monitoring app usage (e.g. a therapist reviewing patient usage and changing reminders/ problems within the diary). This is a barrier that needs addressing prior to implementation and could be provided by the company or a relevant charity (currently provided by the National Autistic Society for Brain-in-Hand users with autism), and/or the treating therapist who could provide ongoing monitoring and motivation.

Additional barriers were lack of motivation, inability to identify a personal need for the technology (i.e. poor insight). Although this may be a challenging barrier to overcome, a potential solution ahead of a feasibility study would be to test the technology under optimal conditions (e.g. on specific individuals who had insight into the impact of their injury on functioning and wanted to work towards achieving relevant goals). Adequate training was also important for patients and clinicians, to ensure users were aware of the app functions and how they could use them effectively; a lack of structured training for clinicians was a barrier to use. Before moving to a trial, a training package will need to be developed to ensure that healthcare workers (e.g. rehabilitation therapists) understand the potential uses of Brain-in-Hand, the software and how to support users. This study suggested that the support provided to Brain-in-Hand users was as important as the app itself. Although set-up sessions were provided to acquired brain injury participants in this study, further development to this training package would need to be carried out ahead of a feasibility trial.

Convergence of mixed methods data was important to understand more about who Brain-in-Hand could potentially support and suggest potential outcomes to be measured in a future feasibility study (such as goal attainment, self-awareness, fatigue or anxiety). Individuals recruited to a future study would need to be aware of the impact of their injury and impairments, such that they could set relevant goals and recognise the need for Brain-in-Hand.

The findings of this study suggest that technologies like Brain-in-Hand can be divided into two components (Figure 6): the 'Big T' (context) and the 'small t' (content). The 'small t' refers to how the technology actually works (i.e. its nuts and bolts). It includes the physical components of Brain-in-Hand - smartphone app and online portal. The 'small t' can be thought of as the intervention 'content' and the device that individuals will use. Without addressing barriers associated with this part of the technology, it would not be as effective and sometimes not work at all. Barriers include losing the smartphone, the app not working correctly, losing login details and having no access to a computer to edit the Brain-in-Hand app. The 'Big T', is the system as a whole. As with the content of the intervention, the context is equally important and if barriers associated with this are not addressed, the technology will be less effective or not used. The 'Big T' refers to many interacting components that can either hinder or facilitate successful implementation. Context not only refers to the environment, but also the personal factors such as motivation, insight and capability. Therefore, researchers should consider both when designing and evaluating interventions.

One of the main issues associated with the use and effectiveness of the app is adequate support for users, something which is already provided for Brain-in-Hand users with autism. A 1-year subscription for such users includes 4 h of personalised planning and set-up support sessions, access to Brain-in-Hand software and on-demand remote support from a Response Service (following the press of a red traffic light), which is provided by the National Autistic Society. A potential solution to ensuring adequate support is available for acquired brain injury users is offering a response service via a brain injury charity (e.g. Headway, UK Acquired Brain Injury Foundation), or by a support worker, however this would require additional funding and training. Another solution would be to embed Brain-in-Hand in specialist NHS rehabilitation and support (including out of hours support) funded by the NHS. Brainin-Hand has the potential as an adjunct to NHS rehabilitation particularly as the online cloud enables a healthcare worker, such as an occupational therapist, to see what their patient is experiencing in real time and how (or if) they are managing. This may lead to revised support or rehabilitation strategies, rather than trial and error approaches, which often rely on patient self-reporting over time; this is particularly challenging for patients with memory problems.

The idea of context and content has been corroborated by other researchers, highlighting their importance in

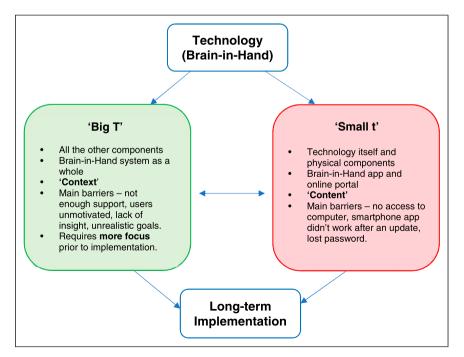


Figure 6. Representation of the two elements necessary for the long-term implementation of technologies like Brain-in-Hand.

implementation<sup>36–38</sup> and influencing rehabilitation outcomes,<sup>39</sup> and are some of the known challenges and barriers to implementation.<sup>14–16</sup> However, there is limited evidence supporting the interaction between the 'Big T' and the 'small t', with many studies focussing only on the environmental context (i.e. setting) rather than the intervention as a whole (i.e. environmental, personal, and technological factors).

One of the main strengths of the study was the A-B case design, which enabled a more in-depth exploration of the data collected from each individual. This design was chosen to understand more about who could benefit most from Brain-in-Hand following acquired brain injury to inform the design of a future trial. This study sits between the theoretical development and the feasibility/pilot phases of the Medical Research Council framework,<sup>40</sup> which are concerned with developing the underlying programme theory for, and identifying the underlying mechanisms of the intervention. Although some participants withdrew, which may have been due to the length of the study and a lack of ongoing support, we saw the 12-months study duration as a strength rather than a limitation because it offered insight into the use of Brain-in-Hand in clinical practice over time and its potential for failure if users were unsupported and goals not reviewed. The integration of methods and the use of convergence coding to determine whether findings converged with or diverged from each other was a further strength, providing insight across cases and findings. It not only highlighted the challenges faced when evaluating complex rehabilitation technologies like Brain-in-Hand but was useful in identifying participant selection criteria, potential outcome measures and issues to address in training and set up for a future trial.

The study has limitations. This was a small study where we aimed to recruit participants with a range of injury severities and breath of problems so that we could identify who (and what impairments) might benefit from using Brain-in-Hand. This was a strength but also a weakness, because the sample was small and heterogenous with no specific focus or similar baseline characteristics, thus a broad set of outcome measures were required. There were minimal changes in the majority of outcomes, which may have been related to the insufficient sensitivity of the measures used (i.e. unable to detect relevant change), the lack of similarity among participants, or a lack of effectiveness of the intervention. The short training period provided to participants in line with the usual practice for Brain-in-Hand (users with autism receive 2 h training) may not have been enough for the acquired brain injury population.

In a future study, participants may benefit from shorter and more frequent sessions over the first 4 weeks, to reinforce learning and facilitate their understanding of its context in everyday life (i.e. how can it help them achieve goals, why do they need to use it, why is the potential of Brain-in-Hand for them long term). This would also provide an opportunity to troubleshoot issues as they arise, thus ensuring users understand all components of the app.

#### Conclusion

Brain-in-Hand did not appear to benefit all people with acquired brain injury who had impaired insight, or poor motivation, however we did note improvements for some individuals. The findings suggest that Brain-in-Hand is more helpful for individuals who have insight into the difficulties presented by their impairments (even if they aren't aware of the extent of them), and individuals with cognitive impairment that require Brain-in-Hand to support planning and decision making. There was also a clear benefit of Brain-in-Hand to improve goal setting and attainment in these individuals. People who reported an improvement in cognitive function, set memory and planning related goals at baseline, suggesting that Brain-in-Hand might be useful for reminding and structuring daily routine. The main barriers to implementation were linked to a lack of or inappropriate support/training, lack of motivation to use Brain-in-Hand, a lack of insight and self-awareness to set realistic goals and identify a personal need for Brain-in-Hand, and technical problems preventing participants from using the app. It is important that both the content and context of interventions like Brain-in-Hand are consistently reported by researchers, so that technology can progress and common barriers avoided. Both the content and context are pivotal to the success of such interventions; however, contextual factors require greater focus during the early stages of implementation research.

There appears to be a potential use for Brain-in-Hand to support this population, however the wider context and infrastructure may be limiting its success. Although, this study sheds light on some the issues Brain-in-Hand could support, further work needs to be conducted to better understand the potential uses of such technology in acquired brain injury.

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#### **Author Contributions**

JK contributed to the main writing of the paper, with additional input from all authors. JK and AW conducted all interviews. Qualitative data analysis was conducted by JK and AW, then reviewed by KR and RdN. Quantitative data analysis and synthesis of data was conducted by JK. All authors critically reviewed the final version of the manuscript for publication. All authors read and approved the final manuscript.

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Questions	Prompts	Links to framework
What do you consider the most helpful aspects of Brain in Hand?	<ul> <li>Was it helpful with things you didn't realise you had problems with?</li> <li>Tell me a bit about your use of the traffic lights <ul> <li>Did you find them useful and how?</li> <li>How could this be improved and would you use it more if it was?</li> </ul> </li> <li>We can see that you haven't really used the problems and solutions feature, why is this? <ul> <li>Do you find other ways of solving daily problems?</li> </ul> </li> <li>What other strategies have you been using to help with ADL? <ul> <li>How did you feel about using the app in public?</li> <li>What would need to be changed for you to use it more?</li> </ul> </li> <li>Can you think about how BiH could help other people with brain injuries? <ul> <li>How could any changes help motivate other appendix</li> </ul> </li> </ul>	Behaviour change wheel - motivation
What problems have you experienced when using Brain in Hand?	<ul> <li>people?</li> <li>Is there anything that has stopped you from using BiH? <ul> <li>How could it be changed to encourage you to complete more tasks?</li> <li>Have you experienced any technical difficulties? (phone not working, no charge)</li> <li>Did you find it difficult to use?</li> </ul> </li> <li>Did you have other strategies in place to deal with your brain injury before the study? <ul> <li>Is BiH better or worse and why?</li> <li>Would you feel happy continuing to use BiH without support of your other strategy (i.e. phone reminders)?</li> </ul> </li> <li>Can you think of any improvements that need to be made to BiH?</li> <li>If these improvements were made, how would you use BiH differently?</li> </ul>	Behaviour change wheel – capability, motivation, opportunity
Can you tell me a bit about people's attitudes towards BiH that you have most contact with?	<ul> <li>use BiH differently?</li> <li>What support have received over the past 6 months when using Brain in Hand from the people around you?</li> <li>Can you tell me a bit about your initial set up and who was present</li> <li>Was it helpful? <ul> <li>Did you feel confident using it after this session?</li> <li>What continuous support have you had and what could you benefit from?</li> </ul> </li> <li>Has it been helpful having a mentor? <ul> <li>If not how could your mentor help you more? Should it be someone different?</li> </ul> </li> <li>Do you think you would have benefitted from additional training and in what way? <ul> <li>Do you think one set up session was enough to explore all aspects of BiH?</li> <li>If you had more support do you think you would have used it more?</li> </ul> </li> </ul>	Behaviour change wheel – opportunity International classification of Health, disability - environmental

Appendix I. Example interview questions for acquired brain injury participants.