

Effectiveness of an electronic cognitive aid in patients with acquired brain injury: a multicentre randomised parallel-group study

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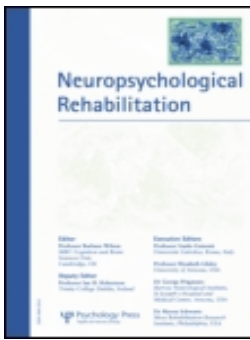
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Effectiveness of an electronic cognitive aid in patients with acquired brain injury: A multicentre randomised parallel-group study

E.A. De Joode, C.M. Van Heugten, F.R.J. Verhey, and M.P.J. Van Boxtel

School for Mental Health and Neuroscience, Maastricht University, Maastricht, The Netherlands

The objective of the study was to examine the effectiveness of a customised personal digital assistant (PDA) as a cognitive aid for people with acquired brain injury, using a randomised parallel-group study. The participants were 34 patients with acquired brain injury in a cognitive rehabilitation setting. The experimental group used a customised PDA, while the control group received care-as-usual (paper-and-pencil aids). Measurements were conducted at baseline (T0), after 8 hours of training (T1), after 16 hours of training (T2), and at 5-month follow-up (T3). The main outcome was the attainment of individualised goals. Both groups showed a significant increase in goal attainment (GAS) ($p < .001$). There were no significant differences between the groups at T1 or T2 on any of the other outcome measures. It was concluded that the

Correspondence should be addressed to C.M. Van Heugten, Department of Psychiatry and Neuropsychology, School for Mental Health and Neuroscience, Maastricht University, P.O. Box 616, 6200 MD Maastricht, The Netherlands. E-mail: c.vanheugten@maastrichtuniversity.nl

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We would like to thank the staff of the participating rehabilitation centres: Rehabilitation Medical Centre Groot Klimmendaal, Arnhem; Sint Maartenskliniek, Nijmegen; Pro Persona Mental Health Care, Wolfheze Adelante, Centre of Expertise in Rehabilitation and Audiology, Hoensbroek Rehabilitation Centre Tolbrug, Jeroen Bosch Hospital, 's-Hertogenbosch; Roesingh Rehabilitation Centre, Enschede; Rehabilitation Centre Heliomare, Wijk aan Zee. Furthermore, we are most grateful to the developers of PEAT, Richard Levinson and Dave Halper, for their support during the study.

customised PDA was as effective as paper-and-pencil aids, and may therefore serve as a useful alternative when choosing the optimal rehabilitation strategy for a patient.

Keywords: Assistive technology; Personal digital assistant; Acquired brain injury; Cognitive rehabilitation; Randomised controlled trial.

INTRODUCTION

Memory, attention and executive functioning are frequently impaired in patients with acquired brain injury (ABI), leading to difficulties in everyday life (Scholte Op Reimer, 1999; Sundet, Finset, & Reinvang, 1988). Such cognitive deficits have been reported in a high percentage of people with hypoxic encephalopathy (Bigler & Alfano, 1988; Caine & Watson, 2000), lacunar infarcts (Van Zandvoort, De Haan, Van Gijn, & Kappelle, 2003), traumatic brain injury (Van der Naalt, Van Zomeren, Sluiter, & Minderhoud, 1999), and stroke. For example, a substantial percentage of stroke patients reported impairments of memory (20%), processing speed (50%) and attention (46%) (Rasquin, Verhey, Lousberg, Winkens, & Lodder, 2002). Such deficits can continue to interfere with daily life functioning even many years after the injury (Barker-Collo, Feigin, Parag, Lawes, & Senior, 2010; Hochstenbach, Den Otter, & Mulder, 2003; Patel, Coshall, Rudd, & Wolfe, 2003; Van Heugten et al., 2000).

Cognitive impairments greatly affect the functioning of patients and also lead to strain, distress, depression and a decreased quality of life for their informal caregivers (Scholte op Reimer, de Haan, Rijnders, & Limburg, 1998; Thommesen, Wyller, Bautz-Holter, & Laake, 2001; Van den Heuvel, 2002; Visser-Meily, Van Heugten, Post, Schepers, & Lindeman, 2005).

Cognitive rehabilitation following brain injury is aimed at managing, reducing and compensating for the cognitive deficits (Carney et al., 1999; Cicerone et al., 2000; Van Heugten, 2001; Wilson, 1997; Wilson, Emslie, Quirk, & Evans, 2001). One of the possible therapeutic strategies in cognitive rehabilitation is the use of assistive technology (AT) to compensate for cognitive impairments.

The use of AT in the form of personal digital assistants (PDAs) has not yet been systematically implemented in cognitive rehabilitation. The only controlled study on the use of PDAs in patients with ABI was published recently, and reported improved timely task completion by patients with TBI (Dowds et al., 2011). The majority of other observations made to date came from single case studies or small, uncontrolled trials (De Joode, Van Heugten, Verhey, & Van Boxtel, 2010). Nevertheless, promising results have been reported, such as improved self-rated performance of everyday life tasks

(Gentry, Wallace, Kvarfordt, & Lynch, 2008) and enhancement of independent behaviour in daily life through the use of electronic devices (Depompei et al., 2008). The efficacy of other types of AT devices has also been studied. An example is the Neuropage, a paging system to compensate for memory and planning deficits in ABI patients. A randomised crossover trial (Wilson et al., 2001) showed that patients were able to learn how to use the Neuropage device and were significantly more successful when using the pager than their counterparts in the control group in terms of carrying out everyday activities such as self-care, self-medication and keeping appointments.

The potential benefit of AT devices for cognitive rehabilitation is, however, not evident for all patients. Certain patient variables should be considered before AT devices or PDAs are used in cognitive rehabilitation. For instance, a PDA may be less appropriate for patients with severely impaired cognitive abilities, who may be unable to learn how to use a PDA or how to deal with unexpected responses of the software, and who do not have the ability to develop effective problem-solving strategies. Previous experience with AT devices by clinician and patient can also be considered a determinant of a positive attitude towards AT (De Joode et al., 2011; De Joode, Van Boxtel, Verhey, & Van Heugten, 2012; Hart, Buchhofer, & Vaccaro, 2004; Hart, O'Neil-Pirozzi, & Morita, 2003).

The most important potential benefits for ABI patients are memory support and task management, as these could strengthen their autonomy and increase their quality of life. Also, PDAs can store large amounts of information relevant for the user's daily routines, information which may be accessed at all times, making patients less dependent on extraneous information sources.

As stated above, despite these potential benefits of AT to support cognitive functioning, no controlled experimental studies have been conducted with PDAs in patients with brain injury, with the exception of the study by Dowds et al. (2011). The aim of the present study was therefore to compare the effects of a customised PDA with those of paper-and-pencil methods (such as notebooks and diaries) in terms of everyday memory, planning abilities, daily life functioning and quality of life in people with ABI. We also examined if the use of a cognitive aid could reduce the burden perceived by the patients' informal caregivers. We undertook a randomised parallel-group trial to address these questions.

METHODS

Study design

A multi-centre randomised parallel-group trial was undertaken to study the effectiveness of a customised PDA. The experimental group was trained in

the use of the PDA, while the control group received care-as-usual, involving the use of paper-and-pencil aids.

After the selection of participants for the study, baseline measurements were administered (T0) and target behaviours were defined. To minimise practice effects on the verbal memory test (VVLT; see below), a dual baseline assessment was administered within two weeks. This was followed by the training course, which had a total duration of 16 hours. Outcome measurements were administered after 8 hours of training (T1) and after 16 hours of training (T2). Follow-up measurements took place 4–6 months after the end of the intervention period (T3).

Participant inclusion

Seven rehabilitation centres throughout The Netherlands participated in the study. The authors contacted 12 centres with the request to participate. Centres were included if they were willing and able to invest sufficient time and effort in the study. The therapists who provided the PDA training course in each centre received at least eight hours of instruction from the first author (EdJ) on how to use the PDA and its assistive software and how to train the patients (see below).

Patients were recruited through the participating rehabilitation centres between September 2008 and September 2010. During this inclusion period, clinicians were asked to evaluate each patient who was eligible for cognitive training to see whether they would be suitable for participation in the study. All of these patients were receiving care as inpatients or outpatients at the time of study. They all had cognitive deficits, as established by their rehabilitation physician or psychologist and had been referred to the rehabilitation centre for cognitive rehabilitation therapy.

Inclusion criteria for patients were: (1) a diagnosis of ABI, (2) age between 18 and 75 years, (3) sufficient comprehension of Dutch, (4) experiencing problems in daily life functioning as a consequence of their brain damage, according to the clinical judgement of the rehabilitation physician and/or psychologist, and (5) a clinical judgement by the rehabilitation specialist that the use of external cognitive aids could be beneficial to the patient (i.e., sufficient level of awareness and cognitive functioning). Exclusion criteria for patients were: (1) visual or manual difficulties incompatible with normal PDA use, (2) severe psychiatric comorbidity, and (3) a progressive neurological disorder.

Inclusion criteria for informal caregivers of patients were: a close relationship with the patient; age between 18 and 75 years; and sufficient proficiency in Dutch to read and understand the questionnaires.

The standing medical ethics committee of Maastricht University Medical Centre reviewed the research protocol and the possible burden for

participants, and approved the study. All patients and caregivers gave their informed consent. The research protocol can be obtained from the corresponding author.

Customised PDA

In order to offer ABI patients the greatest possible benefit from using a PDA, we screened commercially available devices for convenience and adaptability to the patients' individual needs and wishes. After reviewing and comparing several software options such as Handi (Abilia, 2011) and ISAAC (Gorman, Dayle, Hood, & Rumrell, 2003) we opted for the Planning and Execution Assistant and Trainer (PEAT) software (Levinson, 1997) for the current study. The PEAT software was developed for individuals with cognitive impairments. It provides a reminder function and supports enhanced flexibility in the planning of appointments. A "floating task" function allows automatic planning of the specific timing of tasks, as PEAT makes sure the user is not double booked: the software will schedule a task when there is enough time available, and the task is shifted to another time slot if another event interferes. This feature is important to patients with brain injury, who often have difficulties planning, organising and rescheduling daily activities. A "wait button" helps the user to deal with deviations from normal routine, postponing the beginning or ending of a task. Furthermore, users have control over the way they are cued at the beginning and/or end of a task. Each function is customisable to fit the specific needs of each participant using the device. The PEAT software offers the care provider complete control to limit or expand its functionality during the course of the training, based on the progress made by the patient.

There are four main modules in PEAT: cue card, diary, notes section and names section. The cue card shows the current task and the next task, in order to remind the users of current and upcoming events. The diary shows the schedule in a day, week or month view, and users can add or change appointments or to-do tasks. The notes section allows users to take written or voice notes and to link these directly to the relevant appointment or task in the diary. The names section can be used to store contact information, which can also be linked to tasks in the diary. Users are always reminded of the start and end of a task.

The authors translated the software into Dutch in close collaboration with the PEAT developers. For the present study, PEAT was installed on Hewlett-Packard iPAQ HP114 devices, equipped with the Windows Mobile 6 operating system. The PEAT software completely took over the control of the PDA, and users could not switch to the Windows environment, thus ensuring that the user interface was standardised for all patients, and to avoid confusion. Patients received the customised PDA at the start of the training course and

were encouraged to use it as much as possible in order to integrate its use into their daily routines, both at the rehabilitation centre and at home. Patients used the PDA until the post-treatment measurement (T2, after 16 hours of training) had been conducted. At this time, patients in both conditions had the opportunity to buy the customised PDA at greatly reduced price. Patients in the PDA group who did not want to continue using the PDA were advised by their therapist about using another cognitive aid. In some cases, the therapist was able to offer their patient a PDA that was either sponsored by the rehabilitation centre or reimbursed by their personal health insurer.

Intervention procedure

Experimental condition. In the experimental group, “care-as-usual” (normally “paper-and-pencil” diary training) was replaced by PDA training with PEAT. The customised PDA was used to compensate for various cognitive dysfunctions. Memory function was supported by the reminders offered by the PDA, for example, to lock the door before going to bed, lock the door when leaving, take keys when leaving, take out clothes for the morning, make a shopping list, or take medication. Planning and organisation could be supported by planning a busy day in advance, or by using a to-do list. Initiative and attention could also be supported, e.g., through a signal prompting the user to focus attention on an activity, or to start or end a particular activity after a certain period. Finally, predefined scripts could be used to guide the user through several steps of an activity. For example, doing the laundry can be divided into several steps: sort clothes, put them in the washing machine, set the programme, add detergent, start the programme and dry the clothes. Since users could schedule these steps as one task, while the software made sure that every step of the script was performed on time, patients could independently organise these more complex tasks as well.

A total of 16 hours of PEAT training was provided for the participants by therapists at the various rehabilitation centres, according to their centre’s usual procedure. All training courses followed the same initial procedure, based on a predefined protocol, to teach patients how to use the device and what information could and should be entered into it. (The training protocol can be obtained from the first author.) This initial training procedure took between two and six half-hour sessions. The content of the remainder of the training course was tailored to the patients’ specific needs with respect to the use of the customised PDA. The frequency of training sessions varied between two times a week and two times a month. In most cases, the participants received 30–60 minutes of training each week. The frequency and intensity of the training sessions depended on routine procedures at the rehabilitation centre and the needs of each individual patient. Thus, only the total duration of the training was controlled by the researchers.

Control condition. The control group did not use a PDA with PEAT, but instead received “care-as-usual”, aimed at learning skills and strategies to support memory, planning and organisation. Most centres provided training in the use of standard paper-and-pencil aids, such as notebooks and diaries. Although the “care-as-usual” that was offered differed to some extent between centres, most centres gave patients diary training, in which they learned to use a diary, that is, what kind of information they should record, how to structure their day and week and how to integrate diary use in their daily routine. Just as in the experimental condition, the training focused on the specific needs of each patient, although this was limited to the use of a paper diary in the control condition.

The participants in the control condition also received a fixed number of 16 hours of training, which is the average duration for this kind of cognitive training in The Netherlands. The training was always provided by the same professional who also took part in the experimental intervention. The frequency and intensity of the training were the same as in the experimental group.

Mobile phones are increasingly used as prompting devices in cognitive rehabilitation in The Netherlands, and one of the patients in the control group did indeed use a mobile phone as an additional aid, in combination with a paper diary. However, the therapists did not train the control group patients in the use of the mobile phone.

Outcome measures

Main outcome measures

Goal Attainment Scaling (GAS). GAS was the primary outcome measure; it provides an overall outcome assessment by setting individual goals and assessing the level of attainment of these goals after a certain period (Kiresuk & Sherman, 1968). GAS thus enables the use of individualised patient goals as well as being a standardised measurement method. It has been used successfully in studies that included patients with ABI (Bouwens, Van Heugten, & Verhey, 2009). A summary formula is used to calculate the extent to which patients’ goals are achieved (Rockwood, Joyce, & Stolee, 1997). The hypothetical mean GAS score at the time of evaluation is 50 ($SD = 10$), which means that if the post-treatment outcome measurement is between 40 and 60 points, all predefined goals have been met as expected at evaluation. Consistently high or low evaluation scores at the end of an intervention indicate that goals were too easy (score > 50), or too difficult to attain (score < 50) (Gordon, Powell, & Rockwood, 1999).

Cognitive Failure Questionnaire (CFQ). In this self-report questionnaire patients rate the number of mistakes they make per day due to cognitive deficits, such as forgetting names, or problems of attention and concentration (Ponds, Van Boxtel, & Jolles, 2006). The CFQ consists of 25 questions, and patients can rate the frequency of their problems on a 5-point scale (“never” to “very often”); the total scoring range is 0–100, a higher score denoting more everyday cognitive failures.

Frenchay Activities Index (FAI). The FAI assesses a patient’s level of instrumental and social activities (Schuling, de Haan, Limburg, & Groenier, 1993). The questionnaire consists of 15 items and the score ranges from 0 to 45, a higher score indicating better function.

General perceived self-efficacy scale (GSES). The GSES is a 10-item psychometric scale designed to assess the ability to cope with a variety of life demands (Luszczynska, Scholz, & Schwarzer, 2005). It explicitly refers to personal agency, i.e., the belief that one is responsible for successful personal outcomes. The scoring range is 10 to 40, a higher score reflecting a higher self-efficacy level.

Utrecht Coping List (UCL). This questionnaire has been developed to measure the different characteristics of coping style on a 4-point scale (ranging from 1 = “never”, to 4 = “very often”) and consists of 47 items and seven subscales (Schreurs et al., 1993). The subscales represent different coping styles: active approach, palliative reaction, avoidance, seeking social support, passive reaction pattern, expression of emotions, and reassuring thoughts.

Satisfaction with cognitive aid

The participants’ satisfaction with the PDA as a cognitive aid was assessed by determining the percentage of persons in the PEAT intervention group expressing the wish to continue using the PDA after the 16-week training period (T2).

Secondary outcome measures

Centre for Epidemiologic Studies Depression Scale (CES-D). The CES-D is a screening test to identify depressive symptoms (Roberts & Vernon, 1983). The questionnaire consists of 20 items and participants can answer on a 4-point scale, ranging from “rarely or none of the time” to “most or all of the time”. The scale ranges from 0 to 60, and higher scores indicate more depressive symptoms.

MOS Short Form health survey (SF-36). The SF-36 was constructed to assess health status and health-related quality of life (QoL) (Ware & Sherbourne, 1992). It contains 36 items, which may be clustered into two dimensions: physical and mental functioning. The total score for each dimension ranges from 0 to 100, with higher values representing better functioning.

Life Satisfaction Questionnaire (LISAT-9). The LISAT questionnaire assesses a person's satisfaction about important life domains (Carlsson & Hamrin, 1996). It consists of nine items, each scored on a 6-point scale (range: 1 = "very dissatisfied" to 6 = "very satisfied"). The total score ranges from 6 to 54, with higher values representing greater satisfaction.

Caregiver outcome measures

Caregivers also completed the CES-D, SF-36 and LISAT-9, as well as the Caregiver Strain Index.

Caregiver Strain Index (CSI). The CSI (13-item, range 0–13) measures strain related to care provision (Robinson, 1983) for the following major domains: employment, financial, physical, social and time. Positive responses to seven or more items on the index indicate a higher level of strain.

Cognitive assessment

Although no improvement in neuropsychological test performance was expected, a pre- and post-intervention assessment of basic cognitive abilities was performed.

Episodic verbal memory was tested with the Visual Verbal Learning Test (VVLT; Van der Elst, Van Boxtel, Van Breukelen, & Jolles, 2005), a Dutch adaptation of the Rey VVLT (Lezak, Howieson, & Loring, 2004). The total score for all five learning trials and the delayed recall score were recorded.

Executive functioning was tested with the Stroop Color–Word Test (SCWT; Van der Elst, Van Boxtel, Van Breukelen, & Jolles, 2006b), assessing the time needed to complete card III as well as the time difference between card III and card II. In addition, the participants completed the Concept Shifting Test (CST; Van der Elst, Van Boxtel, Van Breukelen, & Jolles, 2006a). This is an equivalent of the Trail Making Test that measures concept shifting and executive functioning. The time difference between Part C (numbers and letters) and Part B (only letters) was calculated. Lastly, participants performed the Letter Digit Substitution Test (LDST; Van der Elst, Van Boxtel, Van Breukelen, & Jolles, 2006c), a test of psychomotor speed and working memory. The number of numbers correctly copied within 90 seconds was recorded.

A cognitive domain was considered as being impaired if one or more scores of the neuropsychological tests for this domain were below cut-off (i.e., $> 1.5 SD$ below the age- and education-corrected mean).

Procedure

After participants and their informal caregivers had been recruited, they were asked to give informed consent. Baseline measurements included demographic variables (i.e., gender, age, education and living situation), injury-related characteristics (i.e., type of brain damage, time since injury and side of brain lesion), and cognitive assessment. After the first baseline measurement, the patient and the informal caregiver completed the outcome questionnaires at home, and returned them at the second baseline measurement. This was also the occasion when the dual baseline measurement for the VVLT was administered and the target behaviours interview was held in order to set the goals for the GAS procedure. This was done by the first author in close consultation with the patient, and if necessary, in the presence of the informal caregiver.

Goals had to be both realistic and attainable for patients receiving cognitive rehabilitation and were not specific to treatment condition, as they were set before randomisation took place. Each patient set a minimum of three goals, and five levels of achievement were specified for each goal. This level ranged from functioning at a level worse than before (score: -2) to achieving the expected outcome (score: 0), and to achieving a higher than expected level of functioning (score: $+2$). For example, one patient wanted to improve the completion of tasks, instead of doing more tasks without being able to complete them. Thus, five levels of achievement were defined, ranging from completing none or only one out of five daily tasks to completing all five tasks every day.

After the two baseline measurements, the patients were randomised to the two groups, using block-wise randomisation with a block size of four, i.e., two participants to the experimental group and two to the control group. Randomisation was done separately for each participating centre. For each centre, four opaque sealed envelopes (a "block") were set aside, each containing a sheet that coded for group assignment. These envelopes were taken to a participant for the randomisation procedure. The participant then chose an envelope in the presence of the researcher and sometimes also the caregiver. The remaining envelopes were taken back to the university and were kept in a locked cabinet until the next participant from this centre was enrolled in the study. Once all four envelopes had been used, a new set of four envelopes was prepared. Blinding of treatment was not possible, due to the nature of the intervention. Outcome measurements were administered by the researcher and were therefore not blinded either. Figure 1 shows the measurement procedure.

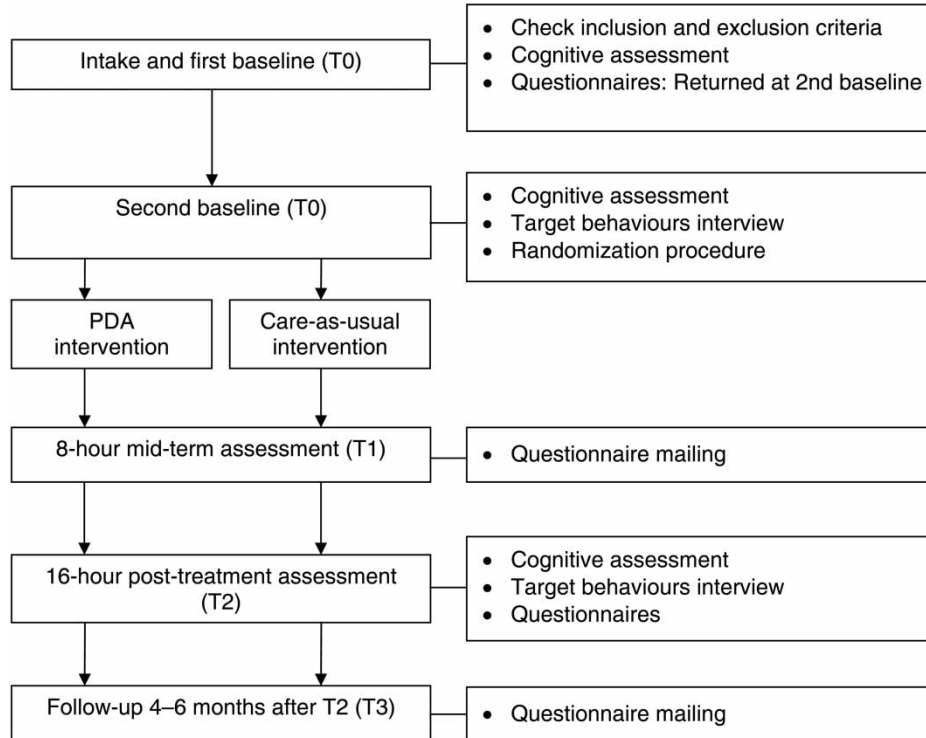


Figure 1. Flowchart of measurement procedure.

Training started within two weeks after the second baseline assessment at T0. The mid-term measurement was administered after 8 hours of training (T1). The questionnaires for this measurement were sent by post. Post-treatment assessment took place after 16 hours of training (T2). The therapists informed the researchers when this number of training hours had been achieved. The patient was subsequently contacted to schedule an appointment for the measurements. These included cognitive assessment, scoring the level of attainment for the GAS goals in a second target behaviours interview and completing the questionnaires. The final follow-up assessment was administered 4–6 months after the end of the treatment (T3), and questionnaires were again sent to the participants by post. The mean (*SD*) time between T0 and T1 was 3.3 months (1.7), the time between T1 and T2 was 4.8 months (3.0), and the time between T2 and T3 was 7.1 months (3.3).

Statistical analyses

Descriptive statistics, including *t*-tests and chi-squared tests, were used to compare the demographic variables, injury-related characteristics and neuropsychological functioning of the two groups at baseline.

Analyses were based on the intention-to-treat principle, which means that patients were analysed according to the group to which they were allocated, irrespective of actual treatment. In addition, per-protocol analyses were performed because some patients stopped using PEAT during the intervention period. Differences in the GAS outcome measurements between the groups at T2 were tested using an independent samples *t*-test. In addition, we tested the differences in GAS scores between T0 and T2 in each group separately, using a post-hoc paired samples *t*-test.

Other outcome measurements were evaluated using repeated measures analysis of variance (T1 vs. T2). The effect of treatment was tested using only the T1 and T2 measurements, since the numbers of patients in the analyses at T3 were limited and some patients had stopped using PEAT while others continued using it, so it was not possible to form subgroups with respect to the effect of the intervention. Group membership was treated in the model as a between-subjects factor, and time of measurement as a within-subject factor.

Statistical analyses were performed with the SPSS statistical software (version 19 for Mac OSX), with alpha level set at .05 for all analyses.

RESULTS

Participants

The seven participating rehabilitation centres referred 45 patients for participation, 40 of whom were included in the study and randomly allocated to a

treatment group (Figure 2). In the end, measurements were available for 21 patients in the experimental group and 13 in the control group.

Table 1 shows the patient characteristics, which were comparable between the groups at baseline. Mean time since injury was 27 months shorter in the experimental group than in the control group, but this difference was not significant due to the large variability ($p > .05$).

Table 2 shows the level of neuropsychological functioning at T0 and T2. Significant improvements over time in the VVLT delayed recall and LDST scores were found in the experimental group. However, no differences between the groups were observed at T0 or T2 ($p > .05$).

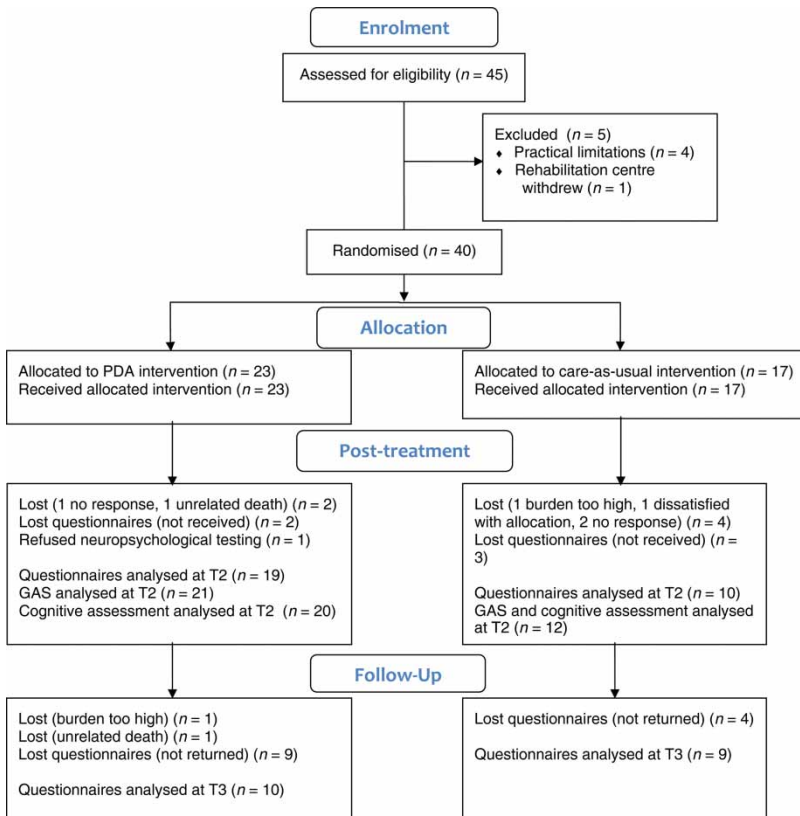


Figure 2. Flow chart of participants in the trial.

TABLE 1
Patient characteristics

		Experimental group (n = 21)	Control group (n = 13)
Men: n (%)		14 (67%)	10 (77%)
Age in years at baseline: mean (SD)		42.2 (15.4)	39.4 (15.6)
Time since injury in months: mean (SD)		38.9 (42.4)	65.9 (117.1)
Education	Low: n (%)	4 (19%)	4 (31%)
	Intermediate: n (%)	12 (57%)	6 (46%)
	High: n (%)	5 (24%)	3 (23%)
Cause of injury	Stroke	7 (33%)	5 (38%)
	TBI	6 (28%)	5 (38%)
	Brain tumour	1 (5%)	2 (15%)
	Mixed stroke/TBI	2 (10%)	1 (8%)
	Other cause ^a	5 (24%)	0 (0%)

TBI: traumatic brain injury; ^a Meningitis (n = 1), chronic toxic encephalopathy (n = 1), combination stroke and tumour (n = 3). No statistically significant differences were found between the groups on any of the variables.

Treatment effects

GAS

Figure 3 shows the mean GAS scores at T0 and T2 for both groups. One participant in the control group was unable to formulate goals for the GAS, most likely due to a lack of insight. Both groups showed improvement in the attainment of set goals between T0 and T2: the experimental group showed a mean increase of 45.2 (SD = 32.8) points, $t(20) = 6.31$, $p < .001$, while the control group showed a mean increase of 36.7 points (SD = 15.6), $t(11) = 8.16$, $p < .001$. However, scores did not differ significantly between the groups at T2 ($p > .05$). Since three participants stopped using PEAT and used a standard aid instead, we also performed per-protocol analyses. These analyses showed results similar to those of the intention-to-treat analyses.

Other outcome measures

Table 3 shows the mean scores on the other outcome measures for both treatment groups. Our repeated measures analyses found none of these outcome measures to differ significantly between the groups at T1 or T2 ($p > .05$). In the per-protocol analyses, however, the results showed an interaction effect between time of measurement and group membership for one secondary outcome measurement: the CES-D. Participants in the experimental group showed a decrease in depressive complaints over time, while the

TABLE 2
Mean neuropsychological functioning at T0 and T2, including percentage of patients with a deficit

		<i>Experimental group</i>				<i>Control group</i>			
		T0 <i>n</i> = 21	Deficit ^a	T2 <i>n</i> = 20	Deficit ^a	T0 <i>n</i> = 13	Deficit ^a	T2 <i>n</i> = 12	Deficit ^a
VVLT (words)	Encoding	38.4 (12.1)	23.8%	42.0 (12.2)	19.0%	41.5 (8.7)	7.6%	44.8 (20.2)	7.6%
	Delayed recall	6.4 (3.8)	47.6%	7.6 (3.9)*	42.8%	7.2 (3.3)	38.5%	7.9 (3.8)	30.8%
SCWT (seconds)	Card III	132.7 (57.6)	42.9%	106.3 (50.6)	33.3%	147.6 (54.2)	53.8%	133.7 (43.4)	38.5%
	Card III-II	54.6 (47.8)	n.a.	37.3 (43.2)	n.a.	68.6 (39.3)	n.a.	55.7 (28.7)	n.a.
CST (seconds)	Part A: 1 concept	27.7 (11.1)	n.a.	23.7 (7.4)	n.a.	29.4 (18.2)	n.a.	27.9 (9.1)	n.a.
	Part C: 2 concepts	46.7 (20.3)	38.1%	44.5 (19.6)	23.8%	40.5 (11.6)	30.8%	41.4 (13.3)	15.4%
	Interference part C-A	19.0 (15.1)	n.a.	20.1 (16.5)	n.a.	11.1 (22.0)	n.a.	13.5 (11.7)	n.a.
LDST (digits)	90 seconds	39.2 (12.7)	61.9%	44.3 (12.7)**	38.1%	38.8 (13.0)	69.2%	41.0 (14.4)	61.5%

VVLT: Visual Verbal Learning Test; SCWT: Stroop Color Word Test; CST: Concept Shifting Test; LDST: Letter Digit Substitution Test; ^a < 1.5 *SD* below mean norm score; n.a.: not available. **p* < .05; ***p* < .01.

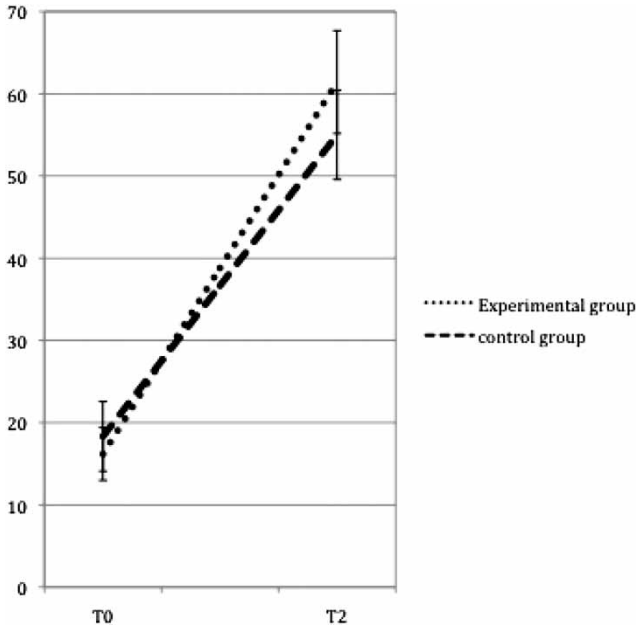


Figure 3. Goal Attainment Scores (GAS) pre- and post-treatment: Mean and standard error.

control group showed an increase in complaints, $F(1,3) = 5.24$, $p = .032$. After correction for multiple testing (Bonferroni correction), however, α was .0036 and this difference was no longer statistically significant.

Caregivers

Four of the 34 patients did not have an informal caregiver. Of the remaining 30 caregivers, 25 agreed to participate. Their mean age was 49.6 years ($SD = 11.2$). Eighteen caregivers were allocated to the experimental group and seven to the control group. They were partners, parents, or siblings of the patient. None of the caregiver outcome measures was found to differ between the groups at T1 and T2. However, the high dropout rate (three in the experimental group and four in the control group) meant that the control group became too small to test statistically for between-group differences.

Satisfaction with cognitive aid

The percentage of participants in the experimental group who chose to continue using a PDA or smartphone after the conclusion of the trial was 57.1%. Although the participants were able to buy the PEAT software at a

TABLE 3
Mean (SD) outcome scores per study group at different time points

		<i>Experimental group</i>				<i>Control group</i>			
		<i>T0</i>	<i>T1</i>	<i>T2</i>	<i>T3</i>	<i>T0</i>	<i>T1</i>	<i>T2</i>	<i>T3</i>
<i>Patients (n)</i>		(20)	(19)	(19)	(10)	(13)	(10)	(10)	(9)
CFQ total		45.8 (15.2)	42.7 (15.4)	42.2 (15.9)	48.4 (10.6)	49.1 (11.2)	46.9 (20.0)	49.2 (14.8)	45.4 (15.1)
FAI total		19.3 (10.7)	21.2 (9.1)	23.0 (7.6)	25.6 (7.4)	23.4 (5.9)	22.0 (7.2)	20.9 (7.3)	24.3 (8.0)
UCL	Active reaction	15.3 (4.4)	16.6 (4.1)	15.8 (4.4)	15.1 (5.8)	15.5 (2.3)	15.5 (3.3)	15.0 (3.6)	14.7 (3.7)
	Palliative	16.9 (3.3)	17.3 (3.4)	17.2 (2.3)	16.2 (3.5)	18.8 (3.9)	19.3 (4.1)	19.2 (5.1)	19.2 (3.8)
	Avoidance	17.3 (4.6)	16.6 (4.9)	16.9 (4.8)	17.4 (3.6)	17.6 (3.7)	17.7 (3.2)	17.3 (4.3)	19.1 (3.7)
	Social support	13.6 (4.3)	13.3 (3.5)	13.3 (3.2)	12.2 (3.2)	11.6 (3.6)	11.9 (3.1)	12.4 (3.7)	12.2 (2.8)
	Passive	12.7 (3.7)	12.0 (3.8)	11.9 (3.4)	12.5 (3.8)	14.5 (4.2)	15.1 (4.7)	16.4 (5.9)	15.9 (5.9)
	Expression of emotions	6.5 (1.5)	5.9 (1.4)	7.1 (1.7)	7.2 (1.3)	5.9 (1.7)	6.0 (1.4)	6.3 (1.7)	6.6 (1.4)
	Reassuring thoughts	11.1 (2.5)	10.8 (2.6)	11.6 (2.3)	10.8 (2.5)	10.8 (2.2)	10.7 (2.3)	10.6 (3.1)	10.8 (2.8)
CES-D		18.2 (6.3)	17.9 (7.4)	18.0 (8.9)	19.3 (7.8)	19.9 (4.9)	19.0 (5.9)	20.2 (6.2)	19.0 (7.7)
SF-36	Physical functioning	44.7 (7.7)	43.7 (10.1)	43.9 (9.9)	46.7 (8.4)	45.7 (10.2)	51.3 (8.0)	45.6 (7.2)	48.1 (12.1)
	Mental functioning	38.6 (13.3)	40.1 (12.1)	39.6 (13.2)	36.9 (12.2)	35.5 (10.8)	34.8 (12.6)	34.8 (13.3)	35.5 (11.6)
GSES		26.3 (5.6)	25.3 (5.2)	25.0 (6.7)	25.9 (6.5)	26.5 (5.9)	25.1 (6.4)	25.3 (6.4)	25.2 (6.2)
LISAT-9		40.4 (7.3)	39.1 (7.5)	39.2 (6.7)	40.1 (5.3)	33.9 (8.1)	35.0 (7.8)	32.3 (7.8)	32.6 (6.1)
<i>Caregivers (n)</i>		(18)	(15)	(15)	(9)	(7)	(4)	(3)	(4)
CES-D		17.3 (6.9)	17.7 (7.9)	15.3 (5.9)	16.2 (5.4)	18.3 (5.8)	15.8 (2.1)	15.6 (2.0)	14.5 (3.3)
SF-36	Physical functioning	49.6 (10.8)	50.5 (11.7)	51.5 (11.6)	53.2 (10.6)	52.1 (6.0)	53.8 (10.4)	53.1 (8.8)	53.8 (6.7)
	Mental functioning	43.5 (9.9)	45.0 (8.3)	44.0 (11.4)	45.1 (9.8)	46.2 (10.9)	46.3 (7.4)	42.2 (3.8)	52.1 (6.2)
LISAT-9		44.8 (6.4)	43.5 (6.4)	41.0 (5.7)	41.1 (4.4)	42.6 (3.7)	41.8 (2.4)	41.5 (0.7)	44.7 (1.5)
CSI		6.8 (3.3)	7.5 (3.2)	6.4 (3.8)	7.7 (4.1)	8.8 (3.7)	6.5 (4.9)	6.3 (5.0)	4.8 (2.6)

CFQ: Cognitive Failure Questionnaire; FAI: Frenchay Activity Index; UCL: Utrecht Coping List; CES-D: Centre for Epidemiologic Studies Depression Scale; SF-36: MOS Short Form health survey; GSES: General perceived self-efficacy scale; LISAT: Life Satisfaction Questionnaire; CSI: Caregiver Strain Index.

90% reduced price, the main reasons for participants not to continue their use of PEAT were that it was too expensive to buy for themselves (19.0%) or that they preferred to use another, cheaper aid (23.8%). The software did not operate error-free during the trial, and glitches in the software and hardware caused frustration to some of the participants in the experimental group, although all of these issues were dealt with within a week. Examples of these technical difficulties were the temporary inability of the device to recharge or to add a new task to the schedule, loss of the charging device or unexpected (at least for the user) “change in the schedule” allegedly caused by the software.

In the control group, the majority (76.9%) chose to continue using a paper-and-pencil aid. However, three participants in this group (23.1%) said they would consider buying PEAT or another PDA or smartphone system.

The difference in satisfaction rate between the experimental and control groups was not statistically significant, $\chi^2(1, 34) = 1.4, p = .24$.

Three participants in the experimental group stopped using PEAT after T2. Two participants felt the PEAT training was too demanding for them and one participant became too frustrated by the glitches in the software and hardware to continue using the device. The per-protocol analysis of satisfaction rate showed a higher satisfaction rate in the experimental group (66.7%) as compared to the intention-to-treat analysis, while the satisfaction rate in the control group was about the same (76.5%). The per-protocol analysis showed no statistically significant differences in satisfaction rate between the treatment groups, $\chi^2(1, 34) = 0.9, p = .34$.

DISCUSSION

This is one of the first randomised parallel-group trials to examine the effects of using a customised PDA as a cognitive aid for patients with acquired brain injury (ABI). Patients with ABI in both intervention groups attained their pre-defined goals, but the success of the intervention in the PDA group did not differ significantly from that in the paper-and-pencil group. No effect of time or treatment group was found on the other outcome measures.

Attainment of personal goals did not result in a higher quality of life or a greater sense of self-efficacy. The lack of difference in effect may be related to a number of factors, such as the small groups, the short duration of the intervention, the low training intensity and the use of standard questionnaires. The focus of GAS is on what participants aim to attain at a personal level, and these goals are most likely the driving force behind their motivation to receive cognitive training. But measuring an effect on the other outcome measures, e.g., on quality of life, may be more difficult as these outcomes are secondary

to a change in behaviour, and may also be influenced by factors other than the actual treatment received in this study.

The effect of both interventions appeared to be similar, which means that we cannot conclude that the use of a PDA was more effective than that of the usual external devices, such as notebooks. We can only conclude that a PDA could be considered as an equally effective alternative to standard paper-and-pencil aids. This is nevertheless an important result in the light of our previous finding that some professionals and caregivers believe that the use of PDAs may not be suitable for ABI patients (De Joode et al., 2012).

The only previous randomised trial in this area of research (Wilson et al., 2001) showed that patients using a pager were more successful in daily tasks than the control group that did not use the device. In the current study we did not find a significant difference in target behaviour attainment between the experimental and control groups. However, the control group in the study by Wilson et al. did not receive treatment (waiting list), while in the current study the experimental intervention was compared with care-as-usual.

Recently, a report was published about the results of an eight-week controlled trial studying the effect of the use of two types of PDA on the timely completion of predefined tasks (Dowds et al., 2011). In contrast with the present study, these authors found a significant increase in completed tasks when a PDA was used as a reminder aid. However, the use of the PDA, the study sample, and the duration and outcome measures were different from those in the current study. First and foremost, patients in the study by Dowds et al. were assisted in entering the appointments in the PDA, to make sure that the reminder would be activated at the right time and with an audible prompt. This is comparable to the way the *Neuropage* was used in a study of its efficacy (Wilson, Emslie, Quirk, Evans, & Watson, 2005), in which message prompts were programmed by others, and patients were only instructed how to react to the prompts. In the present study, no such control was exercised over the input of the reminders. This could be a reason why the use of the PDA was less effective in our study than in the study by Dowds et al. Furthermore, it is not clear if the samples in these studies are comparable, as Dowds et al. included only patients with TBI with an average to below-average level of neuropsychological functioning. Our study included patients with a variety of ABI aetiologies, and more than half of the subjects were impaired regarding at least one cognitive domain.

The possible influence of age, previous experience with computers, aetiology of brain injury and level of cognitive functioning has been described in previous studies (Evans, Wilson, Needham, & Brentnall, 2003; Fish, Manly, Emslie, Evans, & Wilson, 2008; Thone-Otto & Walther, 2003). Patients of a younger age, those having more experience with computers and those with fewer memory and executive problems are more likely to be successful using an electronic memory aid. Less than half of the patients in

both treatment conditions in our study had a clinically relevant memory deficit regarding encoding or delayed recall. This raises the question whether the use of a customised PDA would be equally effective in a more severely affected patient sample. Unfortunately, the small sample size in the current study made it impossible to investigate the potential moderating effects of any patient characteristics on the effectiveness of the intervention.

Limitations

Our relatively small sample size makes it more difficult to draw solid conclusions and could account for the general lack of group differences over time. Although seven centres participated in this study, overall recruitment was poor. We suspect that this was partly due to a stringent selection of participants by the professionals at the centres. Since research is not the first priority for most clinicians, coaching and motivating the recruiters seems important for the successful recruitment of participants. However, practical circumstances meant that the total duration of face-to-face contact between the researchers and the therapists was limited, which could have affected the inclusion and dropout rates. The dropout rate among patients was substantial, which might be partly due to them moving from the rehabilitation centre to their home situation during the intervention period, a reduced need for frequent training sessions over time, or the length of the intervention period. Perhaps the decreasing number of hours spent on cognitive rehabilitation and the return to their “normal” daily lives also reduced their motivation to continue their involvement in the study.

Post-hoc power analysis showed that the current sample and the statistical methods we used allowed within/between interactions with a medium effect size to be detected with a power of .81. In other words, an interaction effect between treatment group and time could have been reliably detected. However, the power to detect between-factor interactions with a medium effect size was only .37. The power to detect a main effect of treatment group or time was thus insufficient.

The cognitive device used in this study did not always operate as expected, and glitches in both hardware and software could have resulted in patient dropout or in a reduction of the potential treatment effect. Mobile technology has evolved rapidly since we selected the device and software to be used in this study, and it is expected that newly developed devices will be more stable and less error-prone.

We observed that support and assistance by a caregiver could improve the value of PDAs for individuals with ABI. Their brain injury makes them less able to deal with unexpected responses of calendar software, and they use less effective problem solving strategies (De Joode et al., 2011). It is therefore important to support patients' use of electronic cognitive aids even after the

completion of training at a rehabilitation centre, for instance by providing access to an online helpdesk.

Previous studies have demonstrated that a lack of efficacy of rehabilitation interventions could be due to a response shift counteracting the effects of the treatment (Rasquin et al., 2010). Patients may have been made more aware of their problems by the training programme, which may have a negative effect on their self-reported level of functioning.

Finally, the lack of blinding in the current study has to be taken into account: the effect of the experimental intervention could have been positively biased by expectations among patients, caregivers, therapists and the researcher about the potential superiority of a PDA over standard external aids.

Conclusion

Our results indicate that patients seem to benefit from both PDA-based and paper-and-pencil based cognitive aids, although the effects are restricted to the realm of personal goals measured by GAS. The customised PDA was shown to be as effective as paper-and-pencil aids and can therefore be considered as a useful alternative in cognitive rehabilitation. However, the financial cost of using assistive technology may still be a significant obstacle for a large number of potential users. This financial hurdle should therefore be overcome before assistive technology can be implemented as a part of standard care. The choice of either a digital or a paper-and-pencil cognitive aid should be assessed for individual patients, depending on their specific needs and capacities.

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