# A randomized controlled trial of Assisted Intention Monitoring (AIM) for the rehabilitation of executive impairments following acquired brain injury (ABI).

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***Abstract***

*Background* Acquired brain injury (ABI) can impair executive function, impeding planning and attainment of intentions. Research shows promise for some goal-management rehabilitation interventions. However, evidence that alerts assist monitoring and completion of day-to-day intentions is limited. *Objective* To examine efficacy of brief goal-directed rehabilitation paired with periodic SMS text messages designed to enhance executive monitoring of intentions (Assisted Intention Monitoring, AIM). *Methods* A randomized, double-blind, controlled trial was conducted. Following a baseline phase, 74 people with ABI and executive problems were randomized to receive AIM or control (information and games) for three weeks (phase 1) before crossing over to either AIM or no intervention (phase 2). Primary outcome was change in composite score of proportion of daily intentions achieved. Fifty-nine people completed (71% male; 46% traumatic brain injury) all study phases. *Results* Per protocol cross-over analysis found a significant benefit of AIM for all intentions ($F(1,56) = 4.28$, $P = 0.04$; $f = 0.28$; 3.7% mean difference; 95% CI: 0.1-7.4%) and all intentions excluding a proxy prospective memory task ($F(1,55) = 4.79$; $P = 0.033$; $f = 0.28$, medium effect size; 3% mean difference; 95% CI: 0.3-5.6%), in the absence of significant changes on tests of executive functioning. Intention to treat analyses, comparing AIM against control at end of phase 1 revealed no statistically significant differences in attainment of intentions. *Conclusion* Combining brief executive rehabilitation with alerts may be effective for some in improving achievement of daily intentions, but further evaluation of clinical effectiveness and mechanisms is required.

Key words: Brain Injuries, Rehabilitation, Executive Function

***Introduction***

Impairments in executive functioning are common following acquired brain injury (ABI) involving the prefrontal cortex [1,2], and are associated with poorer functional and social outcomes [3,4]. Executive processes include breaking down a complex goal into a series of ordered sub-goals that determine behaviour, holding the steps and overarching goal in mind, constraining attention and behaviour to the main goal, and weighing its priority against competing demands that may arise [1,5-7]. When a goal cannot be executed immediately it becomes a prospective memory (PM) [8] that does not remain at the forefront of consciousness but remains latent, to be recalled at the appropriate time ('time-based PM'), when the appropriate opportunity arises ('event-based PM') or at some future stage ('step PM' [9]). Prospective memory failure can result from memory difficulties (forgetting the plan), and executive difficulties [8] (failure to act despite memory of one's intention, also known as 'goal neglect' [10]). Rehabilitation of executive functioning is therefore inherently challenging because the capacities that maximize adaptive change, including ability to transfer rehabilitation from clinic to everyday life, are compromised, resulting in reduced effectiveness of rehabilitation[11-13], and poorer emotional outcomes [14].

Interventions for executive deficits such as Goal Management Training (GMT [5] [15]) emphasise effective implementation of intentions to varying degrees. Typically run in groups over 8 or more sessions GMT includes education to develop awareness and structured practice of goal setting, self-monitoring, and managing competing distractions [16]. Reviews of intervention studies favor metacognitive strategy training (incorporating self-monitoring and self-regulation)[17] and approaches combining GMT with other strategies such as supports for transfer into daily life[16] over stand-alone goal management. The latter review concluded 'proof of principle' was demonstrated for studies of 'content free' cues provided at random intervals for improving goal-directed behavior during brief (10-15 minute) complex office-based tasks[18,19]. However, whilst the international INCOG guideline for rehabilitation of executive impairment supports use of metacognitive strategy training[20], the INCOG guideline for rehabilitation of attention deficits[11] states that evidence is conflicting and further clinical outcome studies are required. A functional imaging study failed to find beneficial effect of periodic alerts on the Sustained Attention to Response Task (SART), but did show reduced right dorsolateral prefrontal activation during provision of alerts. This was interpreted by the authors as indicating that cues assisted the maintenance of intentions by reducing reliance on specific endogenous control processes underpinned by the right fronto-parietal control and attention networks, involved in sustaining attention to task goals[21]. A recent trial[22] found GMT incorporating text message reminders resulted in gains on self-report and neuropsychological measures, although the independent contribution of cueing was not evaluated. Previous trials have used questionnaires or neuropsychological tests rather than real-world behavioural measures to evaluate outcome. In one exception to this Fish et al[23] evaluated transfer of training on a naturalistic task of remembering to make phone calls at set times each day over a 2 week period. Participants with ABI learned specified times to call the study's pausing current activity to mentally review one's intentions was linked with a cue phrase ("STOP"; Stop, Think, Organise, Plan). STOP cues were provided on randomly selected days at random intervals. Cued days were associated with significantly more, and more accurately timed, calls than non-cued days. Although promising for potential application in rehabilitation, the effectiveness in terms of participants' own everyday intentions and potential effect on emotional outcomes were not evaluated. Further evaluation of the effect of combined brief GMT and cueing on everyday goals is therefore required.

Here we report a trial examining the efficacy of Assisted Intention Monitoring (AIM) comprising brief GMT followed by randomly-timed SMS text messages, for improving achievement of everyday intentions. The broad aim was to extend prior research using GMT plus periodic alerts to evaluate potential efficacy in improving achievement of everyday intentions. The primary outcome was a composite score of proportion of 'all intentions' achieved, made up of different types of intention and an objectively scored proxy task (the phone task). The primary study hypotheses were:

1. Proportion of all intentions achieved will be significantly greater during AIM than control phases.

2. Proportion of all intentions achieved excluding the phone call task will be significantly greater during AIM than control phases.

A subsidiary hypothesis was that increased goal attainment would be associated with improved self-rated mood. Exploratory analyses were planned to identify factors that might influence response to intervention, a necessary process in the development of complex healthcare interventions[24].

## Method

### *Ethics*

Ethical approval to conduct the study was provided by a National Health Service Research Ethics Committee (study reference 08/H0306/45) and the relevant Research and Development Department for each of the health services involved in recruitment of participants. All participants provided written informed consent to participate.

### *Trial design*

The study employed a randomised, controlled, parallel group crossover design with three phases (baseline phase, intervention phase 1, intervention phase 2) each of which lasted 3 weeks, with a one week break between phases for completion of measures (phases shown in Figure 1). Assessments and primary analyses were conducted blind to group allocation. Following consent, participants completed initial assessment questionnaires and neuropsychological tests and were supported in identifying daily intentions to be monitored for the study duration . They were then randomized to either AIM or control for intervention phase 1 (equal numbers in each), after which they crossed over to phase 2, during which 'AIM-first' participants received no intervention or usual care and ‘control-first’ received AIM. A conceptually symmetrical cross-over was not possible for the AIM-first group because messages from the study had already been associated with reviewing intentions. The cessation of messages to the AIM-first group in phase 2 therefore allowed examination of whether their receipt was relevant to efficacy of goal management. This design also ensured that all participants had access to an intervention hypothesized to be useful, minimized the possible confounding effect of group differences on treatment effects, provided increased power to detect effects, and allowed examination of the maintenance of any gains in the AIM-first group.

FIGURE 1 ABOUT HERE

A Steering Group comprising researchers, the local NHS Research and Development manager and a person who had sustained a brain injury oversaw study management. The trial was conducted in accordance with National Institute for Health Research (NIHR) Good Clinical Practice in research guidelines, was adopted by the United Kingdom Clinical Research Network (UKCRN) and registered onto their research portfolio (study ID: 5368).

*Participants*

Participants were recruited from UK community services in the East Anglia region, the Cambridge Cognitive Neuroscience Research Panel (CCNRP; a group of people with ABI who have agreed to be approached for relevant research studies) between February 2009 and August 2011. Healthcare professionals working with ABI patients were asked to provide potential participants with information about the study and seek their consent to be contacted by the research team. Members of the CCNRP were contacted directly by the researcher.

Inclusion criteria were as follows:

- aged 18 or over
- non-progressive brain injury, acquired in adulthood
- more than one year post-injury
- clinician, carer or self-reported everyday organization and memory problems
- able to use a mobile phone

Exclusion criteria:

- memory impairment of sufficient severity to limit retention of intentions and training information (clinical judgment and neuropsychological assessment)
- patient or carer participant with severe and enduring mental health problem, or substance misuse or dependency, as identified by referring clinician
- participation in a rehabilitation intervention with significant overlap with the study intervention

*Interventions*

Interventions were delivered by a member of the research team (EG), a qualified occupational therapist with significant experience in providing cognitive rehabilitation interventions in both clinical and research settings with people with stroke and acquired brain injury. TM, a co-author of the Goal Management Training materials, provided supervision.

Assisted Intention Monitoring (AIM)

Brief GMT was provided by EG in participants' homes or a community setting on a one-to-one basis over 2 sessions not more than 5 days apart each lasting between 90 and 120 minutes. Training materials were selected from the full GMT program (as described by Levine and colleagues[5,6,15]) and presented on a laptop as a Powerpoint presentation with accompanying workbook. The slides selected covered the following topics supported with discussion of examples drawn from the workbook or provided by the participant:

- utility of setting goals and breaking goals into steps (Module 1) – e.g. breaking a large goal or problem such as planning a trip away into doable steps
- absentmindedness and 'slip-ups' (Module 2) – e.g. walking into a room and forgetting what you went there for and discussion of factors that can increase slips such as fatigue

- using the 'mental blackboard' to take note of goals and steps (Module 5) – e.g. rehearsing the mental visualization of written or pictorial checklist of steps on a 'blackboard'
- checking the status of one's intentions (Module 9), which was linked with the acronym "STOP" (Stop, Think, Organize and Plan) – e.g. discussing how periodically stopping and thinking about our intentions can help us to stay on track.

The training was provided to the point where the trainer was confident the participant understood the material and the STOP acronym, so the training period varied depending on the knowledge and abilities of the participant. Participants were told that after training they would receive eight "STOP" texts each day, designed to increase the frequency of such reviews. These occurred at random points between 08:00 and 18:00 each working day. They did not occur within thirty minutes of each other or a set phone call time (see below). Messaging was provided via a reminding service [25] with the capacity to send SMS text messages.

Control Intervention

This involved one-to-one sessions (also provided by EG) of the same duration as AIM consisting of brain injury information[26] (excluding reference to executive functioning) presented using Powerpoint, and a computerized visuo-spatial game involving increasingly speeded mental rotation ('Tetris') plausibly linked to improving cognitive skills but not hypothesized to improve prospective memory. Participants in the control phase also received eight daily SMS text messages reading: ‘AIM research study. Please ignore’.

*Measures*

Assessment and screening measures

Standardized neuropsychological assessments were completed and demographic and injury-related data collected. The National Adult Reading Test (NART)[27] was used to derive an estimate of pre-morbid general intelligence. The Speed and Capacity of Language Processing (SCOLP)[28] was used to assess speed of processing. Non-verbal reasoning abilities were assessed with the Matrix Reasoning subtest of the Wechsler Adult Intelligence Scale, 3rd Edition (WAIS-III-UK)[29]. Immediate and delayed verbal recall was assessed using the Logical Memory subtest of the Wechsler Memory Scales (WMS-III-UK)[30]. Executive functioning and attention were assessed using the Letter Fluency part of the Verbal Fluency subtest (Delis-Kaplan Executive Functioning System; D-KEFS)[31], the Sustained Attention to Response Test (SART)[32,33] and the multipart Hotel Test[18] (similar to the 6 Elements [34]). The Coping Inventory for Stressful Situations (CISS)[35] which has been validated for use with ABI[36,37], was included to identify possible moderators of treatment response.

Primary outcome

The primary outcome was the mean daily proportion of intentions achieved by a participant averaged over the final two weeks of each three-week study phase (consistent with previous studies[23,25] data from the 1st week were excluded due to novelty effects). The primary outcome measure was a composite of participants' own, ongoing 'set' intentions, established at initial assessment with the researcher and set for the study duration; participants' 'ad-hoc' intentions, one-off tasks that might arise during the course of the study; seven 'fixed' intentions set to ensure compliance with study procedures (e.g. make sure mobile phone is with you, charged, and switched on); and the phone task[23] described below. With the exception of the phone task, participants recorded success or otherwise in a structured diary and relayed this information to the research team in a daily phone call initiated by the researcher (according to preference this could be via less frequent phone calls, no fewer than 3 per week, or via email). This was also used to determine if goals were irrelevant (e.g. 'remembering keys and wallet when going out' would be 'irrelevant' on a day intentionally spent indoors).

At initial assessment participants were asked to nominate 3 times of the day when it would be convenient to make a brief call to the study's answerphone. These had to be at least 30 minutes from a previous phone call and not set to coincide with a memorable time of day. Participants were asked to make their calls as close to the set-time as possible over the 9 weeks of the study phases (i.e. time-based PM) in addition to one further phone call at an unscheduled time each day (i.e. step PM). Participants were simply asked to state their name on connection. Attainment and timing accuracy were scored from answerphone records. Scheduled calls made within 5 minutes (+/-) of the target time scored 6. This decreased by 1 for each additional five-minute discrepancy down to 1 (+/- 25 out) and 0 (call missed completely). Unscheduled calls gained 1 point if they were made at all, a further point if they were more than 30-mins from another call and a final point if they were made at a different time to the unscheduled call on previous days of the study. Not all calls were possible on all days due to phone malfunction, poor signal, or clash with important activity, and accordingly the score was based on the proportion of the score achieved out of the total score attainable that day.

For each day, the total number of relevant intentions for each participant in each intention type (set, adhoc, fixed and phone calls) was summed and the daily proportion attained calculated. These values were then averaged across each 2-week assessment period.

### Secondary outcome

Given expectations that the phone-call task would benefit from AIM, our second planned comparison considered attainment of all goals excluding the phone-call task.

### Subsidiary measures

Subsidiary measures were administered after each baseline and intervention phase. The Profile of Mood States[38] total mood disturbance (MD) score was used to evaluate the impact of AIM on overall emotional functioning. The Hotel Task and Verbal Fluency were used to evaluate effect of AIM on executive functioning in the absence of cues.

*Randomization*

The randomization procedure was administered by the academic department of one of the authors (JJE) at a site remote from the main research site. Blocked sequences (6 and 4, via www.randomization.com) enabled equal numbers of participants to be allocated to each group. Only one investigator (JJE) was able to access the sequence and allocation, which remained concealed until the researcher delivering the interventions (EG) requested the next participant allocation code, which was provided via email. Allocations were not revealed to any other member of the study team, clinical staff in recruitment sites or participants.

*Analysis and sample size calculation*

Hypotheses 1 and 2 were tested with cross-over analyses conducted on the complete dataset on per protocol basis using repeated measures ANOVA, the within-subject factor being study phase (post-intervention 1 vs. post intervention 2), between-subject factor group (control-first vs AIM-first) with baseline scores as a covariate. Significant group by phase interaction effects were taken as indicating relative efficacy of the AIM intervention. A power calculation for this design carried out using G Power[39] with $\alpha = 0.05$, 80% power, 2 groups and 1 covariate based on detection of a medium-large effect size (as previously found[24], and to identify potentially clinically meaningful response), indicated a sample size between 52 ($f = 0.40$) and 67 ($f = 0.35$) would be required, we therefore sought to recruit 60 participants. The same analysis was conducted on Hotel and Verbal

Fluency test data to explore effect of AIM on executive functioning. Group comparisons post intervention phase 1 between AIM-first and control-first groups, on both intention to treat (ITT; including data from all participants analyzed according to their initial group assignment regardless of whether or not they withdrew) and per protocol (PP; analyzing data only from participants who completed intervention in accordance with protocol) bases, were also conducted. Significant correlates of response to intervention (*P* <= 0.015, α corrected for multiple comparisons) were identified for inclusion in a multiple regression.

## Results

### *Participant characteristics*

Enrolment and allocation information is provided in Figure 1. Eligibility screening was carried out for 93 people, 74 proceeded to randomisation, and 60 participants completed the study, with 58 participants completing the trial and all outcome measures, one further person completed only the daily intention diary, and another completed only the POMS. In the PP group, cause of injury was predominantly Traumatic Brain Injury (TBI; 27, 46%) or stroke (21, 35%). Severity of injury was obtainable for 15 (55%) of TBI participants (severe 11, 41%; moderate, 2, 7%; mild 2, 7%). Notable differences (PP and ITT) were found in pre-injury employment and time since injury, and (ITT only) work hours (see Table 1).

*Hypotheses 1 and 2: Cross-over analyses*

Hypotheses 1 and 2 were tested with repeated measures ANOVA to identify presence of group by time interaction effects in favor of AIM, as planned. Mauchly's Test of Sphericity for equality of variances were not significant and missing data were excluded. Figure 2 shows changes in performance for AIM-first and control-first groups across all phases, for all intentions and also all intentions excluding the phone call task. For hypothesis 1, the repeated measures ANOVA yielded a statistically significant group by time interaction ($F(1,56) = 4.28$, $P = 0.04$; $f = 0.28$, medium effect size; 3.7% mean difference; 95% CI: 0.1-7.4%); participants achieved a greater proportion of intentions during the AIM intervention relative to control. For hypothesis 2 the ANOVA was repeated without the phone-call data and again indicated greater goal attainment with AIM ($F(1,55) = 4.79$; $P = 0.033$; $f = 0.28$, medium effect size; 3% mean difference; 95% CI: 0.3-5.6%). Analysis of phone task data replicated the previously reported advantage of cueing on this task ($F(1,56) = 9.904$; $P = 0.003$; $f = 0.41$, large effect size; 7% mean difference, 95% CI 2-11.8%).

In terms of subsidiary analyses, no significant group by time interaction effect was found for the POMS MD score ($F(1,55) = 0.091$; $P = 0.76$; $f = 0.04$, negligible effect) nor measures of executive functioning (Hotel Test: $F(1,52) = 0.080$; $P = 0.78$; $f = 0.03$, no effect; Verbal Fluency: $F(1,51) = 0.719$; $P = 0.4$; $f = 0.12$, small effect).

*Group differences post intervention phase 1*

Data summarizing group differences post intervention phase 1 are provided in Table 2. For analysis, missing data were excluded, and Levene's test for equality of variances was not significant. No significant differences on 'all intentions' were identified with ITT ($P$ = 0.87; 1% mean difference, 95% CI: -9 - 11%) or PP analyses ($P$ = 0.688; 1.4% mean difference, 95% CI: -5.6% - 8.8%; $d$ = 0.11, negligible effect; 7% observed power). A significant difference in favor of AIM was found on the phone task with PP ($t(57)$ = 2.031; $P$ = 0.047, 9% mean difference, 95% CI: 0% – 18%; $d$ = 0.53, medium effect size; 51% observed power) but not ITT analysis ($P$ = 0.43; 5% mean difference, 95% CI: -8% - 18%).

*Exploratory analyses*

To examine factors that may have influenced response to treatment, simple correlations between possible predictor variables (age, time since injury, avoidant coping style, POMS MD) and change (AIM - Control difference for all intentions and phone task) were conducted. The only near-significant correlation (at corrected $P$ <= 0.015) was between POMS MD at baseline and change in achievement of all intentions ($r$ = 0.28; $P$ = 0.032), multiple regression was therefore not conducted. Differences between injury etiology groups' (TBI n = 27, stroke n = 21, other ABI n = 11) response to intervention were explored with repeated measures ANCOVA (group x injury type x phase; covariates were baseline performance and time since injury). Significant interactions were detected between study phase, injury type and group ($F(2,51) = 5.62$, $P = 0.006$) for the phone task. Tukey's post-hoc pairwise comparisons revealed significant differences between the TBI and 'other ABI' groups (mean difference .20; $P = 0.014$), with the TBI group showing the hypothesised response to intervention on the phone task, the stroke group appearing to drop with removal of AIM more than benefitting from AIM, and the 'other ABI' group appearing to do worse with AIM. Given a previous study found a drop in performance after removal of reminders for stroke, but not TBI participants[40] a one-way ANOVA comparing the three injury type groups was conducted. No significant group differences in pre-intervention executive functioning were found (Hotel Task: $F(2, 54) = 0.169$, $P > 0.05$; Verbal Fluency: $F(2, 53) = 0.014$, $P > 0.05$).

## *Discussion*

### *Interpretation*

This study examined whether AIM intervention was associated with enhanced attainment of daily intentions for people with self or clinician-reported everyday organizational problems and objective executive impairment following ABI. The results show that participants achieved their everyday intentions at a significantly higher frequency during the AIM phases of the study than the control conditions. The findings build upon the body of work that shows randomly occurring periodic cues to prompt 'mental review' of intentions may contribute to improved performance on tasks requiring attentive control of goal directed behaviour[18,19,23]. The results suggest that any benefit of the training offered in AIM was only detectable when participants were receiving cues. Whilst this comparison has a confound of the extra time since training it forms some indication that generalization from training is likely to be enhanced when participants are reminded about it in everyday life. There were no training effects on executive neuropsychological tests (during which cues were not present) suggesting treatment effects are due to compensatory management of, rather than improvement in, executive difficulties. A recent trial[22] found that combined group GMT and reminders resulted in improvements to neuropsychological functioning sustained at 6 month follow-up, suggesting potential benefits of increased intervention time. Fish et al[40] reported independent maintenance of routines after prolonged experience of timed specific reminders, which was evident for TBI participants but not those with stroke, attributed to better executive functions in the former group. In the current study we did not find such group differences in executive functioning although it is important to note the smaller group sizes, participant selection on the basis of poor organisational skills rather than memory, and the use of cues that occurred at random rather than fixed times each day. Further investigation of the treatment duration and intensity required for internalisation of metacognitive or mnemonic cues over time is thus warranted.

Comparing groups post intervention phase 1 there was no evidence of significant benefit of the AIM intervention versus placebo on achievement of intentions or mood (ITT and PP analyses), or performance on the phone task (ITT analyses only), although PP analysis found a benefit of AIM for the phone task. At the most conservative level, this result indicates rejection of the study hypotheses. However, the study was not designed with this analysis in mind, and hence these comparisons were under-powered to detect anything other than large effects. The PP analysis of the effect of training on the phone task at end of phase one did yield favorable results, as did the adequately powered primary cross-over analysis. We have therefore cautiously rejected the null hypothesis, bearing in mind the study limitations, in particular threats to the comparability of groups after cross-over.

There were no significant effects of AIM on POMS mood disturbance scores, suggesting a simple model of enhanced attainment of intentions leading to improved mood may be wrong.

*Limitations*

At 20%, drop out rates were high, contributing to selection bias and limiting generalizability of results. It is likely that this attrition is attributable to aspects of the protocol (daily goal-attainment recording, daily phone calls and long assessment sessions), not the intervention itself. The cross-over design was justified to provide an opportunity for both groups to receive the AIM intervention, for the AIM-first group to have a meaningful control phase, for withdrawal of alerts to be monitored in one arm, and to provide increased power to detect effects of undergoing the intervention. However, this design combined data from the different control phases, compromising the comparability of arms after the point of cross-over. Furthermore it was not possible to examine efficacy of the intervention at follow up.

Randomization produced groups well-matched on primary and secondary outcome measures, neuropsychological functioning or other demographic variables but which differed on time-post injury and employment. Whilst any effect is less problematic for the within-subjects cross-over analysis it may have influenced post-intervention phase 1 analyses. Regarding precision of measurement, the evaluation of real-world impact of the intervention relied upon participants' own ratings in contrast to the phone task, which provided an objective metric of attainment, and therefore may have been a more sensitive measure. Whilst the study was appropriately powered for the analysis of the cross-over data, the subsidiary and exploratory analyses should be interpreted with caution. Finally, a number of statistical analyses were used to address main and subsidiary hypotheses and exploratory analyses. In order to reduce likelihood of false positive results, we limited the number of analyses used to test the primary hypotheses, and specified the directions of predicted relationships. The exploratory findings are reported as tentative.

*Generalizability*

The current study included elements of evaluation of effectiveness such as referral on the basis of clinician, carer or self-identified problems, intervention deliverable within health services, and evaluation of 'real world' outcomes.

However, the delivery of intervention was not tailored to each individual on the basis of specific needs or ongoing response to intervention, and a placebo control condition was included, limiting clinical generalization. Many participants had difficulty with identifying and articulating intentions in precise terms, and results suggested differences in effects depending on etiology, therefore careful thought is needed in clinical application. The relatively brief two-session goal management training adopted here (in comparison with the 14 or more hours of face-to-face GMT training typically reported [16]) might be considered insufficient for many with ABI. Future evaluation of clinical effectiveness, should consider a more extended and tailored period of strategy and self-regulation training [16,17,22] and inclusion in the intervention of additional components that enhance likelihood of transfer of strategies [16,22,41-43].

***Conclusions***

The results of this trial show some support for the efficacy of combining a brief goal management intervention and cueing. Findings are consistent with previous ‘proof of principle’ studies, and have been extended to show some improvement in subjective reports of goal attainment in everyday life. However, when only the initial training period was considered, and when intention to treat was taken into account effect sizes were small or negligible, and not supportive of the efficacy of AIM. The challenge of identifying intentions that are both easy to measure and meaningful to participants may have made detection of effects more difficult. Given the potential effectiveness of AIM, the costliness of neuropsychological rehabilitation interventions, and difficulty transferring skills from rehabilitation to everyday life, further investigation of periodic cues to enhance realization of intentions in everyday life following rehabilitation is warranted.

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## *Conflict of Interest Statement*

The Authors declare that there are no conflicts of interest. TM is a contributing author to Goal Management Training but receives no income from its commercialisation. AB is the manager of the NeuroPage reminding service, but receives no personal income from the service.

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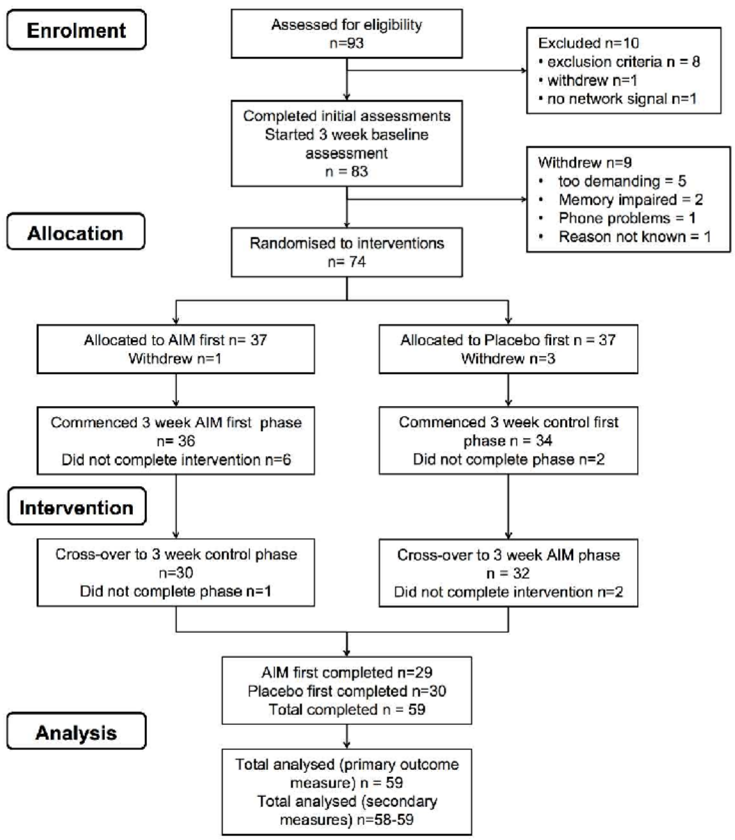


Figure 1: Trial flow chart showing numbers of participants referred, excluded, randomised to intervention, completed and analysed.

FIGURE 1

190x275mm (300 x 300 DPI)

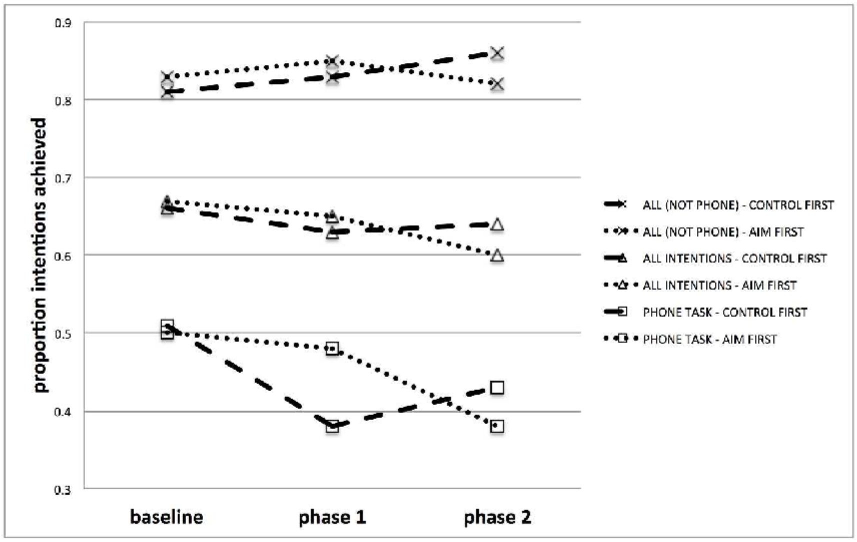


Figure 2: Proportion of intentions achieved for AIM first and control first groups, at baseline, end of intervention phase 1 and end of intervention phase 2 for all intentions, all intentions minus phone task and phone task.
FIGURE 2
297x209mm (300 x 300 DPI)

| | Intention to treat (ITT) | | Per protocol (PP) | |
|---|---|---|---|---|
| | Control First (n=34) | AIM first (n=36) | Control first (n=30) | AIM first (n=29) |
| **Sex** | | | | |
| Male | 23 | 23 | 21 | 21 |
| Female | 11 | 13 | 9 | 8 |
| **Etiology** | | | | |
| CVA | 12 | 11 | 11 | 10 |
| Infection | 1 | 2 | 1 | 2 |
| TBI | 16 | 17 | 14 | 13 |
| Tumor | 4 | 6 | 4 | 4 |
| Missing | 1 | 0 | 0 | 0 |
| **Vocational situation** | | | | |
| Paid work | 10 | 7 | 9 | 6 |
| Retired | 4 | 8 | 4 | 8 |
| Voluntary | 8 | 3 | 7 | 2 |
| Unemployed | 11 | 18 | 10 | 13 |
| Missing | 0 | 0 | 0 | 0 |
| **Work hours** | | | | |
| Full-time | 7** | 4 | 6 | 3 |
| Part-time | 11 | 4 | 9 | 3 |
| Unemployed | 16 | 28 | 15 | 23 |
| Missing | 0 | 0 | 0 | 0 |
| **Pre-injury employment** | | | | |
| Professional | 21** | 12 | 19** | 10 |
| Elementary / service | 10 | 23 | 10 | 19 |
| Unemployed | 1 | 0 | 1 | 0 |
| Missing | 2 | 1 | 0 | 0 |
| **Mean age (S.D.)** | 50.18 (12.76) | 46.36 (14.88) | 49.76 (12.94) | 47.79 (14.72) |
| **Mean years of Education (S.D.)** | 12.47 (2.65) | 12.69 (2.92) | 12.43 (2.67) | 12.79 (3.01) |
| **Mean time since Injury (S.D.)** | 8.62** (8.60) | 4.89 (5.02) | 9.15** (8.70) | 5.00 (5.03) |

| | | | | |
|---|---|---|---|---|
| **D-KEFS Letter fluency** [a] | 7.94 (3.65) | 7.97 (4.01) | 7.67 (3.58) | 7.86 (4.02) |
| **WMS-III LM I**[a] | 9.12 (3.44) | 9.11 (3.56) | 8.97 (3.61) | 8.83 (3.52) |
| **WMS-III LM II**[a] | 9.24 (3.57) | 8.94 (3.87) | 9.07 (3.63) | 8.55 (3.71) |
| **NART**[a] | 103.94 (14.42) | 101.00 (12.89) | 102.73 (14.83) | 102.00 (11.55) |
| **SCOLP Speed of comprehension**[a] | 8.85 (3.54) | 8.36 (3.25) | 8.81 (3.67) | 8.45 (3.29) |
| **SCOLP Spot the word**[a] | 10.82 (3.33) | 9.88 (2.91) | 10.63 (3.47) | 10.03 (2.91) |
| **WAIS-III Matrix reasoning**[a] | 11.79 (3.03) | 12.31 (3.25) | 11.73 (2.97) | 12.93 (2.96) |

| INTENTION TO TREAT | Control first (n=34) Mean (S.D.) | AIM first (n=36) Mean (S.D.) | Mean difference (95 % CI) *P* |
|---|---|---|---|
| **Primary outcome** | | | |
| Overall intention attainment | 0.63 (0.21) | 0.64 (0.17) | 0.01 (-0.09-0.11) *P*=0.87 |
| *Missing Values- Frequency (%)* | *3 (9%)* | *4 (11%)* | |
| **Secondary outcome** | | | |
| Mean daily proportion of non-phone intentions achieved | 0.83 (0.17) | 0.85 (0.13) | 0.05 (-0.06-0.10) *P*=0.62 |
| *Missing Values- Frequency (%)* | *3 (9%)* | *4 (11%)* | |
| Mean daily proportion phone score | 0.42 (0.28) | 0.47 (0.24) | 0.05 (-0.08-0.18) *P*=0.43 |
| *Missing Values- Frequency (%)* | *4 (12%)* | *4 (11%)* | |
| POMS MD | 47.3 (37.9) | 47.2 (40.6) | -0.02 (-19.37-19.34) *P*=1.00 |
| *Missing Values- Frequency (%)* | *2 (6%)* | *2 (6%)* | |

| PER PROTOCOL | Control first (n=30) Mean (S.D.) | AIM first (n=29) Mean (S.D.) | Mean difference (95% CI) *P*-value |
|---|---|---|---|
| **Primary outcome** | | | |
| Overall intention Attainment | 0.63 (0.21) | 0.65 (0.18) | 0.014 (-0.056-0.084) *P*=0.35 |
| *Missing Values- Frequency (%)* | *0* | *0* | |

| | | | |
|---|---|---|---|
| **Secondary outcome** | | | |
| Mean daily proportion of non-phone intentions achieved[x] | 0.83 (0.18) | 0.85 (0.13) | -0.011 (-0.065-0.042) *P*=0.68 |
| *Missing Values- Frequency (%)* | *1 (3%)* | *0* | |
| Mean daily proportion phone calls | 0.38 (0.27) | 0.48 (0.24) | 3.38 (0.001-0.179) *P*=0.047 |
| *Missing Values- Frequency (%)* | *0* | *0* | |
| POMS MD | 2.83 (20.3) | -0.55 (25.6) | 3.38 (-8.78 – 15.54) *P*=0.58 |
| *Missing Values- Frequency (%)* | *1 (3%)* | *0* | |