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Knowledge translation intervention to improve evidence-based practice behaviour of allied health professionals: A cluster randomised controlled trial and 2-year follow-up study

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CHAPTER 3

RANDOMISED CONTROLLED TRIAL

METHODS

Overview

This chapter presents the methods of a cluster RCT that investigated the effectiveness of a KT strategy with a range of AHPs by describing:

- 1) Aim and hypotheses
- 2) Trial design
- 3) Ethical approval
- 4) A description of the eligibility criteria and exclusion criteria for the study
- 5) Methods of blinding
- 6) Methods and rationale of cluster randomisation
- 7) Development and theoretical background of the KT intervention
- 8) The interventions that the KT intervention and control groups received
- 9) Details of the primary and secondary outcome measures
- 10) Procedures for the RCT
- 11) Information regarding data cleaning, sample size calculations and statistical analysis.

Aim and hypotheses

The primary aim of this study was to measure the effectiveness of a KT strategy to change EBP behaviours, knowledge and attitudes of AHPs. The following hypotheses were devised for testing.

EBP behaviour

At the primary end-point:

- 1) Allied health professionals that participate in an 8-week KT strategy will have a behaviourally meaningful and statistically significantly higher self-reported EBP behaviours measured by GAS T-scores than the control group.
- 2) Allied health professionals that participate in an 8-week KT strategy will have statistically significantly higher peer-reported EBP behaviours measured by GAS T-scores than the control group.
- 3) Allied health professionals that participate in an 8-week KT strategy will have statistically significantly higher per person web hits on the EAS measured by web statistics, than the control group.

EBP knowledge

- 4) Allied health professionals that participate in an 8-week KT strategy will have statistically significantly higher EBP knowledge exam scores than the control group.

EBP attitudes

- 5) Allied health professionals that participate in an 8-week KT strategy will have statistically significantly higher EBP attitude scores on the EBPAS than the control group.

Trial design

A multi-site single-blinded, cluster RCT was conducted with AHPs at the Cerebral Palsy Alliance. RCTs are considered the gold standard design to determine whether a given intervention is effective.^{174,175} Figure 4 summarises the basic trial design.

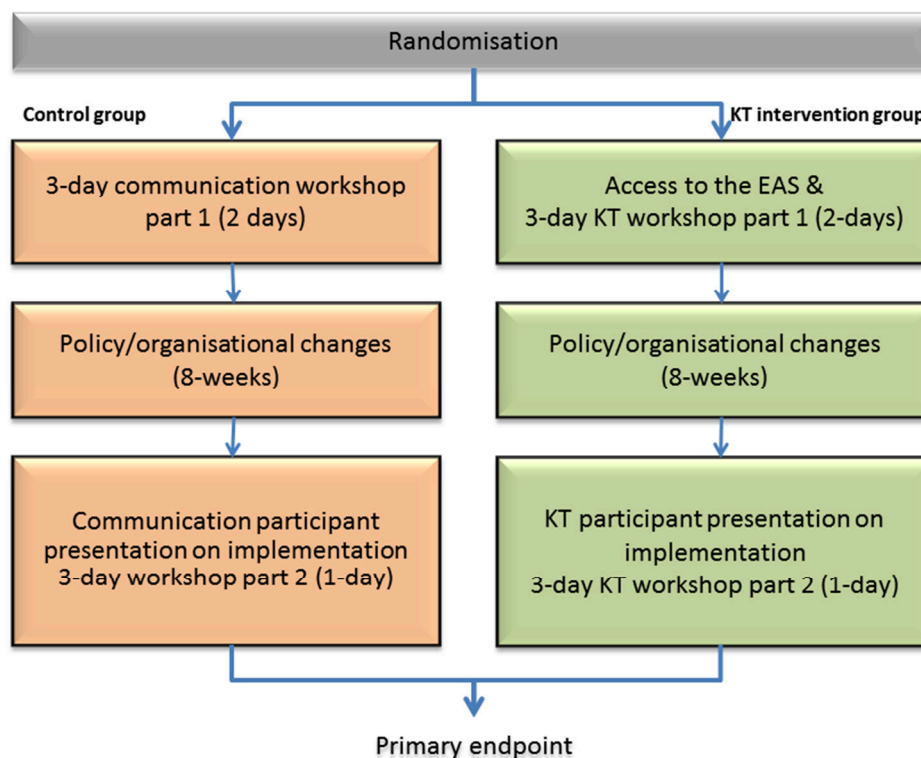


Figure 4: RCT trial design

Setting

Cerebral Palsy Alliance is a not-for-profit organisation providing a range of community-based interventions to people with cerebral palsy in New South Wales (NSW), Australia. NSW is the most populous state in Australia with approximately 7.25 million people (32% of Australia's total population). Cerebral Palsy Alliance had 16 localities across NSW, organised into 4 geographically distinct regions where AHP services were provided. Each region had centralised management for the sites within its boundaries including clinical seniors, professional development activities and mentoring, and thus were considered natural cluster groupings. Regions were de-identified by assigning a number to each region to ensure confidentiality. The four regions will be referred to as cluster 1, cluster 2, cluster 3 and cluster 4 from this point onwards in this thesis. Staff members within these clusters provided direct client services including physiotherapy, speech pathology, occupational therapy, psychology and social work.

Ethics

The project was approved by the National Health and Medical Research Council Human Research Ethics Committee at Cerebral Palsy Alliance on NSW on 6 May 2009 (Approval number: 2009-05-01), and University of Notre Dame Ethics Committee on 9 September 2009 (see Appendix 2 for National Ethics Application). The study was registered with Australian New Zealand Clinical Trials Registry (ACTRN12611000529943) on 23 May 2011.

An adverse event log was not required because the intervention was educational in nature and therefore posed no risk.

Eligibility

Inclusion criteria for clusters were:

- 1) work sites of the study organisation where AHPs were employed
- 2) work sites where AHPs provided direct client services to people with cerebral palsy.

Exclusion criteria for clusters were:

- 1) worksites where direct client services were not provided, e.g. head office.

Inclusion criteria for participants within the clusters were:

- 1) qualified AHPs
- 2) employed at the study site
- 3) providers of direct clinical services to people with cerebral palsy and their families.

Exclusion criteria for participants within the clusters were:

- 1) managers (staff without any clinical caseload)
- 2) staff members without a formal allied health university qualification, such as project officers or welfare workers
- 3) staff who did not attend work on the days of the study intervention, e.g. annual leave taken.

Blinding

Blinding was judiciously applied wherever pragmatically possible, resulting in a single-blinded trial. This included: (1) independent evaluator-blinding to group allocation and phase of the trial when scoring outcome data, (2) partial participant and facilitator blinding to the specific EBP behaviour of interest to the investigators. Participants and workshop facilitators were clearly aware of the content of the workshops, however were not aware of which intervention (KT intervention or communication skills) was of specific interest to the researchers. Fidelity of the evaluator blinding was not formally investigated.

Although the RCT employed the gold standard design to measure a cause-effect relationship, pragmatic constraints inherent in any educational intervention prevented double-blinding.¹⁷⁶⁻¹⁷⁸

Randomisation

An independent officer not associated with the trial, used Microsoft Excel to generate random allocation numbers to create 4 opaque envelopes based upon simple randomisation without limitations.¹⁷⁹ The independent officer randomly allocated the four geographically distinct clusters to either the KT intervention or control group using the opaque envelopes. Cluster randomisation according to the multiple worksites was chosen for two reasons. First that cluster randomisation reduced the risk of contamination that may have occurred if participants working at the same site had been randomised to different interventions. Second that the workshops were optimally suited to be delivered to whole clusters (for pragmatic and professional reasons). Cluster randomisation occurred before participants were recruited for pragmatic reasons, but group allocation notification was withheld from participants until all clusters were randomised.

Intervention

Assessment of barriers and facilitators

A comprehensive assessment of barriers and facilitators was done over a one-year period. This took the form of meetings between managers, policy makers, researchers, practicing senior clinicians and knowledge brokers; and observation of clinical staff. The barriers assessment, although comprehensive, was informal in nature. The barriers selected were determined by consensus between those involved in meetings throughout the year. As there is no firm evidence regarding the superiority of one KT strategy over another⁶⁵ researchers and knowledge brokers jointly designed the KT strategy based on whether or not the barrier was modifiable by a pragmatically feasible intervention. Modifiable barriers included lack of skill, time, and knowledge. Partially modifiable or non-modifiable barriers were:

- 1) evidence that was considered not clinically relevant
- 2) staff who did not have access to full electronic databases
- 3) some staff had negative attitudes towards EBP.

Modifiable barriers, theoretical underpinnings and strategies for the KT strategy are detailed in Table 4. Details of how the components of our multifaceted intervention correspond to the KTA process are in Table 5.

Development of multifaceted intervention

Strategic planning meetings were held every 6-weeks in the year leading up to the RCT and included researchers, knowledge brokers, policy makers and managers. Knowledge brokers were senior staff with allied health backgrounds (one per discipline employed in the most senior role for each discipline). Policy makers were the senior executive staff and managers, who were involved in direct management of AHPs in the organisation. Goals around EBP behaviours were set and strategies to achieve these goals were jointly selected based on barriers identified in the literature and assessment of the study site.

The EAS formed the basis of our KT strategy and was developed by research staff and knowledge brokers using freely available software (MediaWiki) (see Figure 5 and Appendix 3). Figure 5 outlines the workflow of the steps involved from the AHP's inquiry to the information delivery. The EAS included succinct summaries of all the cerebral palsy research evidence about intervention, prognosis and outcome measurement. Intervention evidence was labeled using the traffic light system^{102,180} where each intervention was given a traffic light color with an actionable message attached. Green = 'Go' if high quality evidence supports the effectiveness of this intervention, Yellow = 'measure' where low quality or conflicting evidence supports the effectiveness of this intervention, therefore measure the outcomes of the intervention to ensure the goal is met, and RED = 'stop' where high quality evidence demonstrates intervention is ineffective or harmful, therefore do not use this approach. LC co-authored a journal paper that used the traffic light system as a KT tool to communicate systematic review finding for 63 cerebral palsy interventions.¹⁸⁰ Decision-making algorithms with embedded evidence summaries were also available on the EAS. Each section of the EAS included abstracts of research articles, descriptions of the intervention/assessment and a hyperlink to the article.

KT intervention group

The KT intervention group received a KT strategy that included: (1) access to the EAS, (2) a 3-day workshop to receive user training, divided into 2 parts 8-weeks apart, and (3) policy/organisational changes designed to overcome EBP barriers (quarantined EBP time, mentoring, compulsory use of outcome measures and documentation changes including reminder systems) made available during the 8-week study period. The KT strategy was both at the cluster level and at the individual level. See Table 5 for details of intervention.

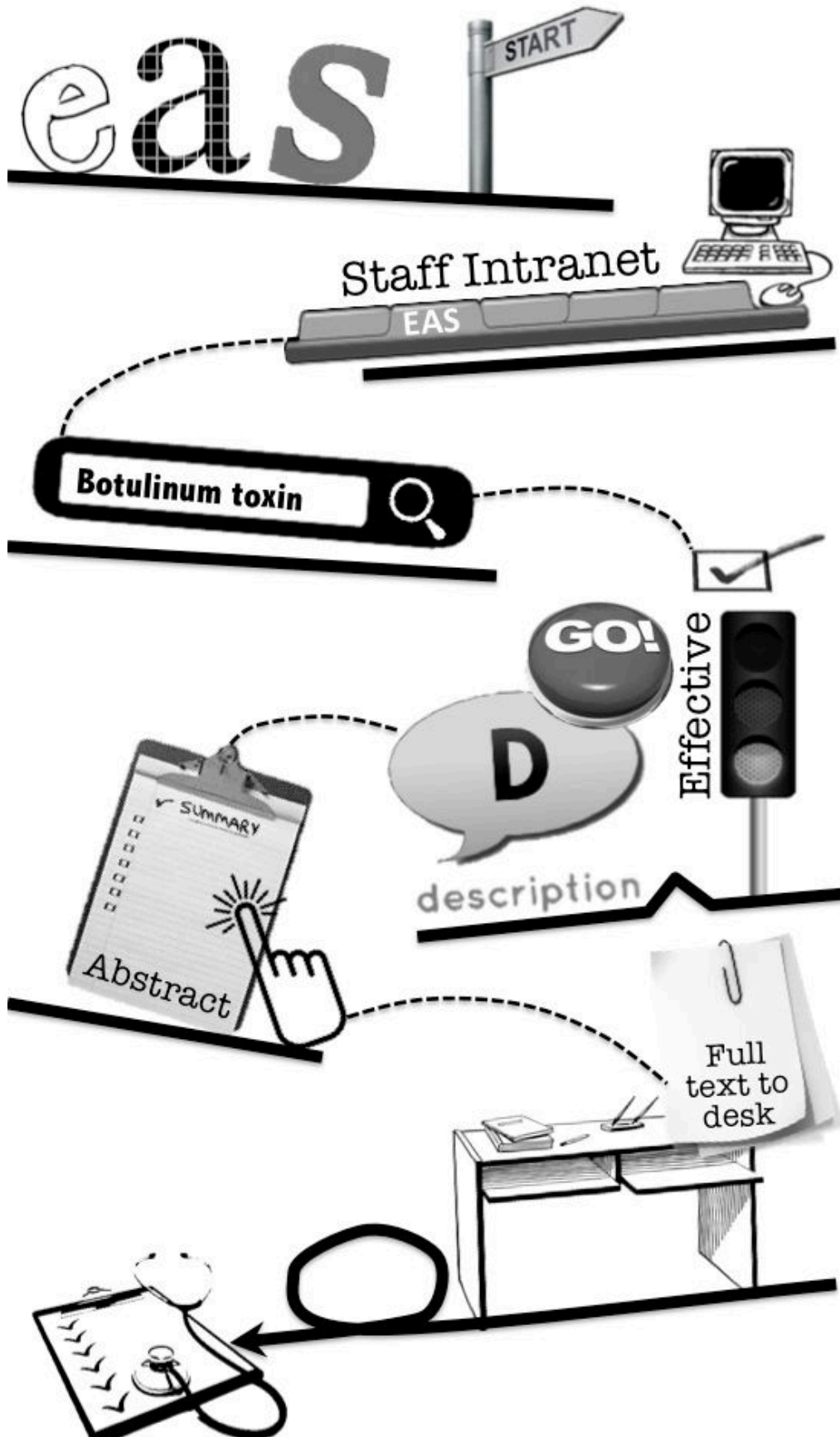


Figure 5: EAS infogram

Table 4: Theoretical basis and strategies to address modifiable barriers

Barrier: Lack of confidence/skill searching, appraising and synthesizing research evidence		
KT strategy	Underpinning theory or group of theories	Strategy/rationale
Workshop	Problem-based learning, learning styles	Workshops used problem-based learning approach and a variety of approaches to ensure that different learning styles were catered to, maximizing the likelihood of increased confidence and skill levels.
EAS	Cognitive	Accurate, relevant research evidence on cerebral palsy assessment and treatment was provided via the EAS building skill by modelling synthesis and summary of treatment areas. The EAS bypassed the need for high-level appraisal skills.
Mentoring	Educational	AHPs were included in the problem solving process during mentoring sessions and aimed to increase confidence and build skill base.
Barrier: Lack of time		
KT strategy	Group of theories that the intervention relates to	Strategy/rationale
EAS	Cognitive	The provision of accurate, relevant research evidence bypassed the need for extensive time spent searching and appraising research via databases and journals.
Paid EBP time in policy	Reimbursement	Paid, protected time for AHPs to engage in EBP activities was provided.
	Leadership	Changing policy suggested management 'buy in' and endorsement to support changes throughout the <u>organisation</u> (leadership theory).
Documentation changes including a reminder system	Total quality management	Patient documentation and work processes were reorganised to support clinical decision making and save time (reminder systems, checklists and directing participants to the EAS).

Barrier: Evidence considered as not clinically relevant		
KT strategy	Group of theories that the intervention relates to	Strategy/rationale
Workshop teaching EAS	Educational	AHPs were involved in the problem solving process, so that they 'owned' and were a part of the process and could see the applicability of the EAS. Having the 8-week period in between workshops, allowed independent learning and time to apply the EAS information to a real client.
	Motivational	Facilitators aimed to convince AHPs of the relevance of research in their area by exploring the EAS through clinical examples and role playing
EAS	Marketing	An appealing product (the EAS) was developed and this was disseminated in a variety of ways (workshop, mentoring, documentation changes).
Barrier: No access to full articles and research databases		
KT strategy	Group of theories that the intervention relates to	Strategy/rationale
EAS	Organisational learning	All staff members at every level of the organisation had access to current cerebral palsy evidence and exchange of information via mentoring sessions and team meetings was promoted.
Barrier: Some staff with negative attitudes towards EBP		
KT strategy	Group of theories that the intervention relates to	Strategy/rationale
Workshop	Social	Credible staff facilitated workshops, modelled positive attitudes and emphasised 'buy in' from decision-makers in the organisation.
Mentoring	Social	Mentors were selected with positive attitudes towards EBP so that target behaviour was modelled.

Access to the Evidence Alert System

The EAS was the cornerstone for all other interventions, representing the central funnel on the KTA.⁵¹ KT intervention group participants were informed about the EAS and educated in using it in the workshop. The EAS was available on the Cerebral Palsy Alliance intranet.

3-day workshop

Workshop – Part 1

Part 1 (2-days) of the workshop provided training to the participants to apply the EAS to decision-making within their daily clinical work.

A series of clinical examples were explored using the interface of the EAS, training about evidence levels, clinical decision-making algorithms and use of two psychometrically sound, cross disciplinary outcome measures.

Training was delivered based on recommendations from systematic review literature that: (1) used a mix of instructional techniques including didactic and interactive styles,^{4,181} (2) encouraged collaboration within and between professional groups¹⁸² (3) used multiple media such including video, simulated clinical scenarios, slideshows and written information,¹⁸¹ (4) ensured multiple exposure to content throughout the entire KT intervention period via different modalities in the workshops, mentoring and the EAS.¹⁸¹

The training content of the workshops provided:

- 1) Research evidence for; (a) goal-setting (b) prognosis (c) interventions (d) modes of service delivery and (e) outcome measurement
- 2) Resources to assist with clinical decision-making including; (a) the cerebral palsy EAS and (b) algorithms/ decision aides.
- 3) Staff supports including; (a) a flowchart describing the service delivery decision-making process, (b) clearly defined staff expectations, (c) position papers to define service parameters, (d)

pathways defining service responsibilities, (e) searchable wiki with evidence summaries

- 4) Skills training with practice in; (a) developing measurable goals, (b) using goal-setting measures, (c) selecting relevant prognostic messages, (d) selecting evidence and (e) selecting relevant outcome measures.

Workshop – Part 2

Part 2 (1-day) of the workshop 8-weeks later involved participants presenting a case study detailing how they used the EAS to inform their clinical decision-making with a real client.¹⁸³ This was followed by discussion with a small group of colleagues designed to help participants demonstrate the integration of their learning into their own clinical work.¹⁸⁴ Investigators and senior clinicians led the workshops using knowledge brokering strategies.¹⁸⁵

Policy changes

Policy changes that were implemented during the 8-week study period included: (1) paid, protected EBP time, (2) at least 1 scheduled mentoring session with EBP trained knowledge brokers,^{5,102,186} and informal mentoring upon request, (3) mandatory use of outcome measures, (4) changes to documentation reminding AHPs to use outcome measures and record the level of evidence for a given intervention. The 8-week implementation period allowed the participants to experience the revised workplace EBP expectations, practice using the EAS with clients, prepare their real world case study for part two of the 3-day workshop and reflect on their changes to practice.²³ The KT strategy was directed at the cluster level (3-day workshop, access to the EAS and policy changes) and individual level (mentoring and 3-day workshop part 2).

Control group

The control group received an equal intensity intervention about communication skills with no EBP content using KT strategies and no use of the EAS. The intervention included: (1) a 3-day workshop about AHP-client communication skills and (2) policy changes (mentoring and quarantined time for communication skills) about communication skills. Health professional-client communication skill training was considered a valuable use of staff time, and is reported to be effective in improving communication skills.^{187,188} The content of the control group workshops were entirely different to the KT intervention group minimising contamination. To further minimise the risk of co-intervention and contamination, the control group was not informed about the EAS, paid EBP time, knowledge brokers or EBP mentoring until the end of the trial. The changes to documentation were not implemented in the control group clusters until the end of the RCT.

Table 5: KT strategy with corresponding KTA phases

KT Strategy	What Part of the KTA Cycle did the Intervention Impact?					Who Implemented It?
	Creating Knowledge	Localising Knowledge	Identifying Barriers	Redressing Barriers	Maintaining Use	
Before RCT						
Strategic planning meetings		✓	✓	✓	✓	Managers Human Resources Knowledge brokers Policy Makers
Policy Changes (policies developed but not implemented until RCT) Provision of paid, dedicated EBP time Provision of a policy endorsed EBP mentoring program Mandated and compulsory use of psychometrically sound outcome measures with all clients embedded in workflow e. g. included within mandatory Individual Family Service Plans		✓		✓		Managers Human Resources Knowledge brokers Policy Makers
Evidence Alert System development	✓					Research Investigators
During RCT (8-weeks; June – Aug 2009)						
Skills Training Workshops (3 days)		✓	✓	✓	✓	Peers Knowledge Brokers Research Investigators
Paid EBP time, mentoring, compulsory use of outcome measures (see policy changes above), documentation changes including reminder systems		✓		✓	✓	Managers Human Resources Knowledge brokers Policy Makers

Primary outcomes

The primary endpoint was change in self-reported and peer-reported EBP behaviour from baseline to 8-weeks measured by Goal Attainment Scaling. Study outcomes were measured at the individual level and cluster level and are detailed with corresponding hypotheses in Table 6.

Goal attainment scaling

Procedure for goal attainment scaling

Participants rated themselves against the self-GAS scales, and then to limit measurement bias, in a separate environment, a well-acquainted peer rated their performance on the peer-GAS scales. The steps involved in setting GAS goals are:

- 1) devising goals/target behaviours that are measurable
- 2) defining a continuum of possible outcomes – worst expected outcome (-2), less than expected outcome (-1), expected outcome (0), more than expected outcome (+1), and best expected outcome (+2)
- 3) specifying the criteria for scoring at each level
- 4) determine current or initial performance
- 5) intervening for a specified period
- 6) determining performance attained on each objective
- 7) evaluating extent of attainment.^{189,190}

The goals in our study were devised by a multidisciplinary panel of experts, familiar with practice behaviours of AHPs. Twenty-five goal scales were developed, half relating to EBP behaviours and the other half relating to communication behaviour as per the controlled comparison intervention (see self-evaluation form in Appendix 5). The questions covered goal-setting behaviour, use of outcome measures and cerebral palsy classification systems, interactions with clients and their families, use of the EAS and

support of research (in our case the Cerebral Palsy Register). The traditionally used 5 point scale (-2 to +2) was expressed on the evaluation form as a percentage of time to reflect how often self- and peer-reported behaviour occurred. These equated to: never and 1–5% of the time (-2), 5–24% of the time (-1), 25–49% of the time (0), 50–74% of the time (+1), 75–99% of the time and always (+2). To obtain the standard raw GAS score, the percentage intervals were directly transposed back into the -2 through to +2 scores as per GAS scoring conventions. Raw GAS scores were then converted to T-scores, enabling inferential statistical analysis of continuous data.

Using a measurement tool that had strong psychometric properties was one of the strengths of our study. That said, the application of GAS in an educational context using percentage intervals to reflect the regularity of a specific behaviour is novel. Systematic reviews reveal a need for educational outcomes to be measured with validated tools.^{152,191,192} One criticism of GAS is that despite users' best efforts, the intervals between GAS levels are not always exactly equal^{161,193,194} making statistical analysis problematic. We overcame this limitation by using percentage intervals within scale descriptors, increasing the rigour of the measurement tool.¹⁶¹

Secondary study outcomes

Open-ended exam questions

Changes in EBP knowledge were measured by open-ended exam questions with pre-set answers based on published evidence. The marking schedule was pre-defined by the multidisciplinary panel of experts and was fully supported by published evidence in cerebral palsy (see Appendix 5 and 7).

Evidence based practice attitude scale

Self- and peer-reported changes in attitudes to EBP were measured using subsets 3 and 4 (with permission from Aarons), as subsets 1 and 2 were not relevant for the context of our study (see Appendix 5).

Use of the cerebral palsy evidence alert system

EAS utilisation was measured by number of web page hits collected via a software program that tracked cluster-specific IP addresses in batches. Web hit data collection was concealed from participants, minimising the likelihood of observer bias affecting EAS use.

Table 6: Hypotheses matched to domain and measurement

Hypothesis	Domain	Instrument	Psychometric properties		Measurement	Data
Allied health professionals that participate in an 8-week KT strategy will have statistically significantly higher self-reported EBP behaviours measured by GAS T-scores than the control group.	EBP behaviours (self-report)	GAS ¹	Valid	Yes	The KT intervention group scores on the self-report evaluation form - GAS EBP, sum of questions 1,3,5,7,9,11, 15,17,19,21,23 converted into a T-score.	Primary outcome measure. Analysis by inferential statistics.
			Reliable	Yes		
			Sensitive to change	Yes		
Allied health professionals that participate in an 8-week KT strategy will have statistically significantly higher peer-reported EBP behaviours measured by GAS T-scores than the control group.	EBP behaviours (peer-report)	GAS	Valid	Yes	The KT intervention groups scores on peer GAS EBP questions 1,3,5,7,9, 11,15,17,19,21,23;converted to a T-score	Primary outcome measure. Analysis by inferential statistics.
			Reliable	Yes		
			Sensitive to change	Yes		
Allied health professionals that participate in an 8-week KT strategy will have statistically significantly higher per person web hits on the EAS measured by a web statistics, than the control group.	EBP behaviours	Frequency of use measured by web hits per person	N/A		The KT intervention group will have more page hits on the wiki than the control group at 8-weeks post intervention.	Secondary outcome measure. Analysis by descriptive and inferential statistics.
Allied health professionals that participate in an 8-week KT strategy will have statistically significantly higher EBP knowledge exam scores than the control group.	EBP knowledge	Exam questions	N/A		The KT intervention group scores on Open ended questions 1,2,5 & 6 will significantly improve but there will be no change in the control group.	Secondary outcome measure. Analysis by descriptive and inferential statistics.

Hypothesis	Domain	Instrument	Psychometric properties		Measurement	Data
Allied health professionals that participate in an 8-week KT strategy will have statistically significantly higher EBP attitude scores on the EBPAS	EBP attitudes	EBPAS ²	Valid	Yes	The KT intervention group's EBPAS score (subset 3 + subset 4) will significantly improve but there will be no change in the control group.	Secondary outcome measure. Analysis by descriptive and inferential statistics.
			Reliable	Yes		
			Sensitive to change	Unknown		

Notes:

¹ GAS = goal attainment scaling

² EBPAS = evidence based practice attitude scale

Procedures and data collection

LC collected data between June 2009 and August 2009 (see Figure 4). The workshops were held at the participant’s worksite or nearby venues with educational facilities large enough to host the entire cluster. The structure and measures of the study are summarised in Figure 6. The procedures and time line for the study are detailed in Table 7.



Figure 6: Study structure and measures

Table 7: RCT study procedures

Date	Procedure
March 2009	Randomisation — clusters randomised to KT intervention group or control group
April 2009	Information sheet — sent to potential all participants via email (Appendix 4)
	KT intervention group
	Control group
June 2009 – Aug 2009	<p>RCT – EBP workshop Part 1 (days 1 and 2)</p> <ul style="list-style-type: none"> • eligible participants invited to participate in study • first author (LC) carried out coordination of voluntary consent • consent forms signed • baseline data collected: <ul style="list-style-type: none"> - participants nominated a codename - participants completed self-GAS, EBPAS and exam questions (Appendix 5) - participants then nominated a colleague (peer) and told them their codename - colleagues (peers) moved to another part of the room to complete the peer-GAS form and EBPAS (Appendix 6) - GAS and EBPAS forms (baseline data) collected - participants attended part 1 of EBP workshop (see Table 5) <p>RCT – Access to EAS and policy changes (8-week period) (see Table 5)</p>
	<p>RCT – Communication skills workshop Part 1 (days 1 and 2)</p> <ul style="list-style-type: none"> • eligible participants invited to participate in study • first author (LC) carried out coordination of voluntary consent • consent forms signed • baseline data collected: <ul style="list-style-type: none"> - participants nominated a codename - participants completed self-GAS, EBPAS and exam questions* (Appendix 5). - participants then nominated a colleague (peer) and told them their codename - colleagues (peers) moved to another part of the room to complete the peer-GAS form and EBPAS (Appendix 6) - GAS and EBPAS forms (baseline data) collected - participants attended part 1 communication skills workshop (Table 5) <p>RCT – Policy changes (8-week period):</p> <ul style="list-style-type: none"> • mentoring by knowledge brokers • quarantined time for communication skills planning and reflection

Date	Procedure
	<div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> <p>KT intervention group</p> </div> <div style="width: 48%;"> <p>Control group</p> </div> </div>
June 2009 – Aug 2009	<div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> <p>RCT – Workshop Part 2 (day 3)</p> <ul style="list-style-type: none"> • participant attended EBP workshop part 2 • end of study data collected: <ul style="list-style-type: none"> - participants nominated a codename - participants completed self-GAS, EBPAS and exam questions (Appendix 5) - participants then nominated a colleague (peer) and told them their codename - colleagues (peers) moved to another part of the room to complete the peer-GAS form and EBPAS (Appendix 6) - GAS and EBPAS forms (8-week data) collected - participants attended part 2 of EBP workshop (see Table 5) </div> <div style="width: 48%;"> <p>RCT – Workshop Part 2 (day 3)</p> <ul style="list-style-type: none"> • participant attended communication skills workshop part 2 • baseline data collected: <ul style="list-style-type: none"> - participants nominated a codename - participants completed self-GAS, EBPAS and exam questions (Appendix 5). - participants then nominated a colleague (peer) and told them their codename - colleagues (peers) moved to another part of the room to complete the peer-GAS form and EBPAS (Appendix 6) - GAS and EBPAS forms (8-week data) collected - participants attended part 2 communication skills workshop (see Table 5) </div> </div>
Nov 2011	Long-term follow-up data-point (see Chapters 5 and 6)

Data cleaning

All items on the self and peer-reported GAS, exams and EBPAS forms were scored using two different methods and then compared to identify and thus correct scoring errors, ensuring the final score was accurate.

Scoring Method 1: All forms were scored manually and entered onto a single, hard copy summary sheet. The total scores were added up by calculator and then entered into Microsoft (MS) Excel by data entry personnel. Error formulas in MS Excel were created to ensure that the correct numbers of items were entered within an expected range of scores. Data entry personnel were trained by myself to enter data and provided with information sheets to ensure consistency of data entry. I conducted spot checks for accuracy for 10% of participants. Two data entry errors were found and each of these episodes involved the correct scores being entered in the incorrect phase of treatment.

Scoring Method 2: Each item score was individually entered into MS Excel by myself. To ensure intra-rater reliability, 10% of evaluation forms were re-scored. No entry errors were found. MS Excel formulas were created to calculate total scores and GAS T-scores.

There were no discrepancies between the scores entered via methods 1 and 2.

Sample size and power

The methodological decision to test the efficacy of an organisational KT strategy within one agency imposed pragmatic limitations on the obtainable sample frame. We successfully recruited 88% of the available sampling frame, however the total number of employees at the agency was less than the number of participants required to reach statistical power if correlation of outcome variables within sites was observed (intra-cluster correlation). A sample size calculation identified the probability of detecting an effect size of 1 at an alpha level of 0.05 (one-tail) and a power of 90%. For Goal

Attainment Scaling [mean T-score = 50, standard deviation (sd) = 10] an improvement of 10-points or more in the KT intervention group than the control group was sought, (improvement of 1 sd). The expert panel agreed that a 10-point increase in GAS T-scores equated to significant clinical improvement in EBP behaviours. The calculation assumed a 20% non-consent rate and a 20% attrition rate indicating a sample size requirement of 72 (38 per group) for a non-cluster trial. We enrolled 135 professionals (n = 73 interventions and n = 62 controls) at 4 sites. Based on estimating an intra-cluster correlation co-efficient (ICC) of 0.1 we calculated that the study was underpowered to demonstrate an improvement of 10 points between groups if a cluster effect of this size was observed (Variance Inflation Figure = 4.3).

Statistical methods

All statistical analysis was carried out with individual participants as the unit of analysis on an intention-to-treat basis by using SPSS for Windows 19.0.0 (SPSS Inc, Chicago, IL) and SAS 9.3 (SAS Institute, Cary NC).

We conducted generalised linear regression analysis for primary and secondary endpoints, using post intervention GAS T-score as the outcome variable and adjusting for potential confounding variables (baseline GAS T-score, profession, group allocation, grade level and years in the disability field). Effect sizes with 95% confidence intervals (CIs) were calculated and significance was set at 0.05. These estimates would underestimate the standard errors and confidence intervals for the effect size if participant outcomes are correlated within cluster sites, thus mixed effects models with cluster included as a random effect were used to adjust for a cluster effect to calculate the effect size for each outcome.¹⁹⁵ ICC was calculated from the mixed effects model and bootstrapping (1000 samples generated) was performed to calculate 95% CIs for the ICC.

Synopsis

This chapter reported the methods of a cluster RCT by describing the hypotheses to be tested, trial design, study eligibility, blinding and randomisation. Details of the development and final KT intervention, along with the intervention that the control group received were then presented. Outcome measurement, procedures for the study, data cleaning, sample size and statistical analyses were detailed. The next chapter presents the results from the RCT.