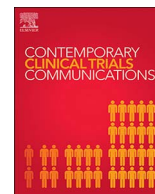




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## Parenting program versus telephone support for Mexican parents of children with acquired brain injury: A blind randomized controlled trial

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### ABSTRACT

**Introduction:** Acquired brain injury (ABI) during childhood typically causes behavior problems in the child and high levels of stress in the family. The aims of this study are: (1) to investigate the effectiveness and feasibility of a parenting intervention in improving behavior and self-regulation in Mexican children with ABI compared to telephone support; (2) to investigate the effectiveness and feasibility of a parenting intervention in improving parenting skills, parent self-efficacy and decreasing parental stress in parents of children with ABI compared to telephone support. Our secondary aims are (1) to explore the impact that parent characteristics have on the intervention outcomes; (2) to investigate if changes are maintained 3 months after the intervention.

**Methods:** The research design is a blind randomized controlled trial (RCT). Eligible participants include children with a diagnosis of ABI, between 6 and 12 years of age, and their parents. Sixty-six children and their parents will be randomly allocated to either a parenting program group or telephone support group. The parenting program involves six face-to-face weekly group sessions of 2.5 h each. Participants in the control group receive an information sheet with behavioral strategies, and six weekly phone calls, in which strategies to improve academic skills are provided. Children and their parents are evaluated by blind assessors before the intervention, immediately after the intervention and 3-months post-intervention.

**Discussion:** This study will be the first to evaluate the efficacy and feasibility of a parenting program for Mexican parents of children with ABI.

**Trial identifier:** ACTRN12617000360314.

### 1. Introduction

Brain damage in early stages of life results in deficits in executive functions (EFs) [2]. EFs are a group of cognitive skills required for purposeful goal directed activity [3]. EFs are largely mediated by the prefrontal cortex [4]. The maturation of the prefrontal cortex networks

underlies the development of EFs, which can be disrupted by the onset of an acquired brain injury (ABI) during childhood or adolescence [5,6]. Impairments in executive functions are often the core deficit in children with difficult behaviour problems [7].

Behaviour problems are associated with deficits in self-regulation [1,8]. Children require SR to follow rules, develop social competence,

**Abbreviations:** AARP, Abbreviated Acceptability Rating Profile-Parenting; ABI, Acquired brain injury; BRI, Behavior Regulation Index; BRIEF-A, The Behavior Rating Inventory of Executive Function Adult Self-report; BRIEF, The Behavior Rating Inventory of Executive Function parent form; CBCL, Child Behavior Checklist; CT, Computed Tomography; CG, Control group; DGT, Delayed gratification task; EC, Emotional control; ECBI, Eyberg Child Behavior Inventory; EFs, Executive functions; ERCL, Emotion Regulation Checklist; FBII, Family Burden Injury Interview; GCS, Glasgow Coma Scale; GEC, Global Executive Composite; IDB, Beck's Depression Inventory; IAST, Inventory Anxiety State Trait; Iskalti, Iskalti Centre of Psychological and Educational Support; MFFT, Matching Familiar Figure Test; MI, Metacognition Index; MRI, Magnetic resonance imaging; PS, Parenting scale; PSI, Parent stress index; PSOC, Parent sense of competence; RCT, Randomised controlled trial; SD, standard deviation; SESBI, Sutter-Eyberg Behavior Inventory; Signposts, Signposts for building better behaviour; SR, Self-Regulation; TEA-Ch 2, Test of Everyday Attention for Children Second Edition; TRF, Teacher report form

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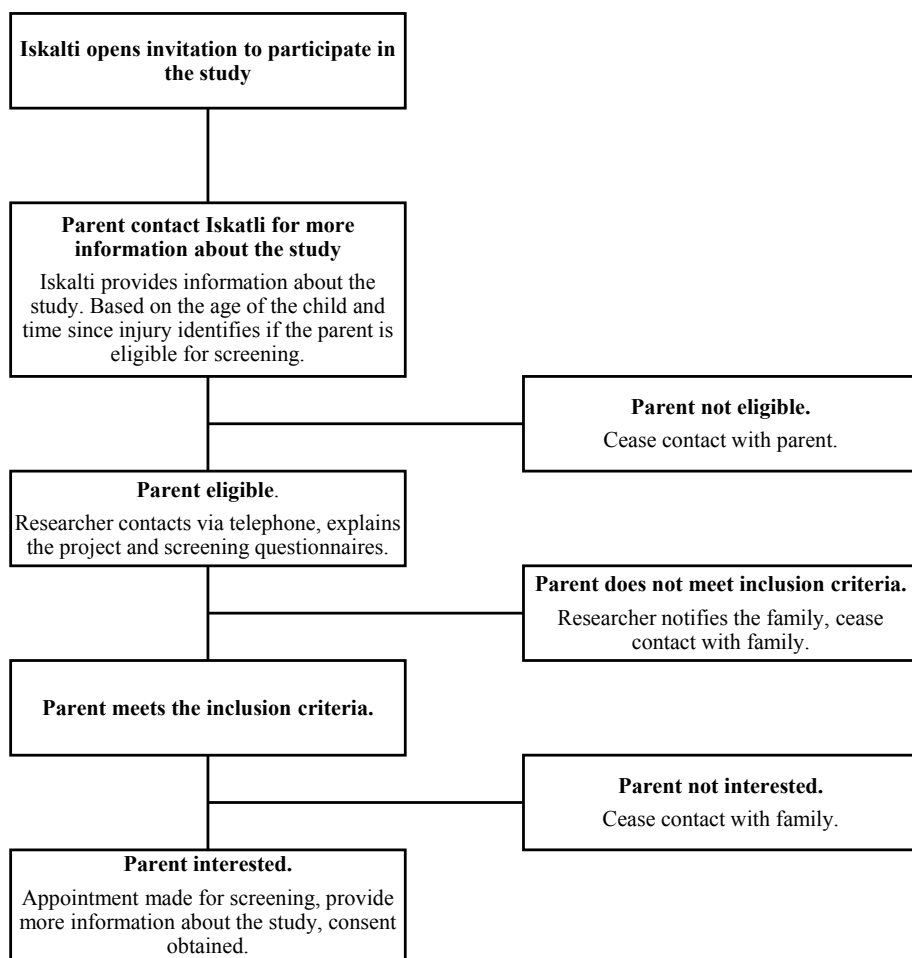


Fig. 1. Recruitment process.

academic skills and adaptive behaviour [9–11]. Children with poor SR are at risk of having attention difficulties, impulsivity, academic difficulties, behaviour problems and poor social skills [12–15]. SR is composed of 3 dimensions: emotional SR, cognitive SR and behavioural SR [8]. Children with a good acquisition of emotional SR are able to recognize emotions within themselves and in others and express emotions depending on the context [16,17]. Cognitive SR includes stopping an initial automatic response, interrupting an ongoing response when it is ineffective and protecting self-directed responses from distraction [13]. Behavior SR is composed of the integration of emotion SR and cognitive SR [18].

Parents can model, and therefore promote SR, in their children [19]. In child rehabilitation the participation of parents is fundamental for effective results. The parenting programme “Signposts for building better behaviour” (Signposts) teaches parents general skills to help them manage their child’s behaviour [20]. Signposts has demonstrated efficacy in preventing and reducing challenging behaviour in Australian children with ABI and improving parental well-being [21]. There is no information about the feasibility and efficacy of parenting programs which aim to reduce behaviour difficulties in Hispanic families with a child with ABI. Mexican parents of children with ABI could benefit from an evidence-based prevention program that helps them to develop parenting skills to manage the difficult behaviour of their child.

## 2. Objectives and hypothesis

Our primary aims are: (1) to investigate the effectiveness and feasibility of Signposts in improving behavior in Mexican children with ABI compared to telephone support; (2) to investigate the effectiveness and feasibility of Signposts in improving parenting skills, parent self-

efficacy and decreasing parental stress in parents of children with ABI compared to telephone support. Our secondary aims are: (1) to investigate the effectiveness of Signposts in improving SR in Mexican children with ABI compared to telephone support group (2) to explore the impact that parent characteristics have on intervention outcomes and (3) to investigate if parenting and child-behavior changes are maintained 3 months after the intervention. We hypothesize that on completion of the Signposts intervention, and at 3-months post-intervention: (i) parents of children with ABI will report improved child behavior and SR compared to those in the telephone support group; (ii) parents of children with ABI will report reduced stress, improved parenting skill and parent self-efficacy compared to the telephone support group; (iii) parenting and child-behavior changes will be improved, with these changes showing maintenance.

## 3. Methods

Research question: Is Signposts feasible and effective in improving the behavior of Mexican children with ABI, improving parenting practices and in decreasing parental stress in their parents?

### 3.1. Trial design

The research design is a blind randomized controlled trial (RCT) with allocation to one of two treatment arms: (1) Signposts program or (2) Psychoeducation sheet regarding behavior management and weekly calls for improving academic skills (CG). Participants allocated to both groups receive the corresponding intervention during the same time span. Once participants complete the follow-up assessment the parents assign to the CG will have the opportunity to receive the Signposts

intervention. The follow-up assessment is completed at 3 months post-intervention.

### 3.2. Study setting

The intervention is conducted at *Iskalti-Condesa*, one of the clinics of Iskalti Centre of Psychological and Educational Support (Iskalti). This clinic is close to the center of Mexico City and is well equipped to conduct neuropsychological assessments and provide the intervention program.

### 3.3. Recruitment

Recruitment commenced in March 2016 and will continue until April 2017. The University of Melbourne Human Research Ethics Subcommittee approved the study protocol (1545487). The recruitment process is detailed below and in Fig. 1. Parents are informed about the research project by a plain language statement during the initial face-to-face interview and signed consent is obtained before the pre-assessment session.

### 3.4. Inclusion and exclusion criteria

The following inclusion criteria are required to participate in the study: (1) Parents must have a child aged between six and twelve years of age; (2) The child has a diagnosis of an ABI (defined as damage to the brain that occurs after birth); (3) Child with a medical reference stating type of brain injury; (4) The injury is diagnosed at least 3 months prior to the start of the pre intervention assessment; (5) Enough medical history to determine injury level of severity (Glasgow coma scale in a medical report or neuroimaging evidence of mass lesion or neurological deficits reported by the treating medical clinician); (6) Mothers or fathers can participate together or individually; (7) Parents must have an active and current parenting role with the child; (8) Parents must be able to comply with the study intervention and assessment protocols as is determine by the researcher during initial contact with the parent; (9) Parents must be over 18 years; (10) Parents must be able to write and read in Spanish. Exclusion criteria include: (1) Parent with symptoms of psychosis or borderline personality (2) Children with incomplete treatment of chemotherapy; (3) Children programmed for surgery; (4) Child receiving other kind of behavior modification therapy; (5) Parent or child with history of psychiatric illness; (6) Uncontrolled seizures in the child; (7) Future neurosurgery programmed for the child; (8) Parent does not have current access to children.

### 3.5. Patient selection

Initial contact with families is via Iskalti to seek permission for a researcher to talk with them. Iskalti recruitment process: (1) Through their website and professional network using a poster and a flyer with general information on the study, Iskalti invites participants that may meet the inclusion criteria; (2) Parents interested in the study contact Iskalti or a researcher via telephone or email; (3) A researcher confirms via telephone if the parents are eligible for screening and provides more information about the study; (4) If the parents are not eligible for the study the researcher makes this clear during the telephone call; (5) If the parents are eligible for the study the researcher provides more information about the study, describe the screening questionnaire, its purpose and how it is link with the randomized controlled trial of the program; (6) If the parent is still interested in participating, an appointment is made to do the screening; (7) Parents with high borderline symptoms are considered ineligible for the study, and if this is the case, the researcher informs the parent and then cease contact with the family; (9) If the parent meet the inclusion criteria and expresses interest in participating in the study, a plain language statement is provided, doubts that may arise about the study are clarified and sign the consent.

### 3.6. Randomization procedures

Randomization occurs once an eligible parent has accepted the invitation to participate in the study and has signed the appropriate consent form. A randomization list was generated by a researcher (B.P.C.) using Microsoft Excel program, where participants are allocated to one of the two treatment arms. The end result will be two randomly allocated treatment arms of equal size.

### 3.7. Blinding arrangements

Researchers involved in recruiting families to the study or delivering the intervention to families are involved in the randomization process. The randomization list is generated by a different researcher (B.P.C.). The researcher involved in recruitment is informed of the allocation and contact the parent to discuss the allocation and plan their enrolment in a group. The researcher conducting the data analysis is not blind to participant identity and allocation. The assessments pre, post and follow up are done by blind assessors. Volunteer-student psychologists, previously trained in the assessment instruments, conduct the assessments under supervision. All of them had a minimum of three years study in the Psychology area and received a 25-h training in which they learned to apply and grade the measures. The assessors give the questionnaires to the parents, assessed the child and score the tests and questionnaires. They are not aware of group allocation and they do not participate in the intervention. All the participants receive Signposts or weekly phone calls. Participants are aware to which study arm they have been allocated because the phone calls focus on academic skills and not on behavior problems. In addition, participants in the CG know that they will be offered the Signposts intervention after completion of the study.

### 3.8. Intervention procedures

#### 3.8.1. Signposts for building better behavior

Signposts is a manualized parenting program that aims to develop skills in parents to improve behavior. In Signposts the parent chooses the goals, measures and monitors the child behaviors, chooses the strategies and evaluates the effectiveness. This parenting program is delivered in 6 weekly sessions of 2.5 h each. The sessions are delivered in groups of a maximum of 8 parents. The main researcher is delivering the sessions, and in each session another clinician is present to provide individualized support in the event that it is needed. Signposts consists of a Workbook, a DVD, and 9 manual modules. However, the Spanish version includes only a workbook translated to Spanish with permission from the Parenting Research Centre, Victoria, Australia, and the module “Dealing with a Head Injury in the Family” translated with permission of Damith Woods [25]. Two Signpost’s certified practitioners reviewed the translation to assure that the content was accurate. The parents are able to take notes during the sessions and a sheet listing the key concepts of the session is provided. The content of the sessions is described in Table 1. To improve adherence with the content of the intervention a

**Table 1**  
Content of the sessions.

| Session | Module  |
|---------|---|
| 1       | Introduction<br>Dealing with a head injury in the family<br>Measuring your child’s Behavior |
| 2       | Systematic use of everyday interactions   |
| 3       | Replacing difficult behavior with useful behavior   |
| 4       | Planning for better behavior  |
| 5       | Teaching your child new skills  |
| 6       | Dealing with stress<br>Your family as a team  |

**Table 2**  
Measures.

| Variable                   | Moment of Assessment |    |    | Who completed the test/<br>questionnaire? | Name of Instrument(s)  |
|----------------------------|----------------------|----|----|---|--|
|                            | T1                   | T3 | T4 |   |  |
| Intellectual coefficient   | ✓                    |    |    | Child                                     | Wechsler Intelligence Scale for Children-IV  |
| Parent self-regulation     | ✓                    |    |    | Parent                                    | Behavior Rating Inventory of Executive Function- Adult Self-report                                 |
| Parent anxiety             | ✓                    |    |    | Parent                                    | Inventory Anxiety State Trait  |
| Parent depression          | ✓                    |    |    | Parent                                    | Beck's Depression Inventory  |
| Disciplinary practices     | ✓                    | ✓  | ✓  | Parent                                    | Parenting Scale  |
| Parent sense of competence | ✓                    | ✓  | ✓  | Parent                                    | Parent sense of competence scale   |
| Parental stress            | ✓                    | ✓  | ✓  | Parent                                    | Parenting stress index (short version)   |
| Child behavior -home       | ✓                    | ✓  | ✓  | Parent                                    | Child Behavior Checklist   |
| Child behavior- school     | ✓                    | ✓  | ✓  | Parent                                    | Eyberg Child Behavior Inventory  |
|                            | ✓                    | ✓  | ✓  | Teacher                                   | Teacher Report Form  |
| Cognitive self-regulation  | ✓                    | ✓  | ✓  | Teacher                                   | Sutter-Eyberg Student Behavior Inventory-Revised   |
|                            | ✓                    | ✓  | ✓  | Child                                     | Matching Familiar Figure Test  |
|                            | ✓                    | ✓  | ✓  | Parents                                   | Metacognition index from Behavior Rating Inventory of Executive Function (BRIEF) parent form       |
| Emotional self-regulation  | ✓                    | ✓  | ✓  | Child                                     | Balloon hunt (children from 5 to 8) or Hector cancellation (children of 8 or older) from TEA-Ch-2. |
|                            | ✓                    | ✓  | ✓  | Parent                                    | Emotional regulation checklist   |
|                            | ✓                    | ✓  | ✓  | Parent                                    | Emotional control subscale from BRIEF-parent form  |
| Behavioral self-regulation | ✓                    | ✓  | ✓  | Parent                                    | Behavior Regulation Index from BRIEF-parent form   |
|                            | ✓                    | ✓  | ✓  | Child                                     | Delay gratification task   |
| Feasibility                |                      | ✓  |    | Parent                                    | Acceptability questionnaire, Percentage of sessions attended and % of homework completed.          |

Pre: Pre-assessment; Post: Assessment after the intervention; F-UP: Follow-up assessment 3 months after the intervention. TEA-Ch-2: Test of Everyday Attention for Children Second Edition.

checklist with the topics of each session is completed during the sessions.

### 3.8.2. Control-group intervention

The participants in the control group receive an information sheet with strategies for challenging behaviors and weekly phone calls for 6 weeks. Each phone call lasts approximately 15 min. During the phone calls exercises which aim to improve academic skills, such as math's or reading are suggested. The academic skill is chosen based on the area of main concern of the parent.

### 3.9. Measures

Parent and child characteristics are measured only before the intervention (T1). Parent and child-outcome measures are completed at T1, immediately after the intervention (T3) and three months post-intervention (T4) (see Table 2). The feasibility measure is completed at T3. Intervention is T2. While, most of the questionnaires are available in Spanish, the researchers obtained consent to use Spanish translations for questionnaires that were not available in Spanish.

#### 3.9.1. Parent characteristics

**Social risk.** Social risk is measured using 3 of the 5 components used by previous studies [26,27]: Family structure (0 = family intact, 1 = separated/dual custody or cared for by another intact family member such as grandparents, 2 = single caregiver or foster care), education of the primary caregiver (0 = tertiary, 1 = completed year 11 or 12, 2 = completed below year 11) and occupation of the primary income earner (0 = skilled/professional, 1 = semi-skilled, 2 = unskilled). Each component has three levels, with 0 being lowest risk and 2 being highest risk. The total score (range from 0 to 6) is used for the analysis, in which a higher score indicates greater social risk.

**Family burden.** Family burden injury interview (FBII) assesses the impact of childhood brain injury on the family [28]. FBII has a high internal consistency with a Cronbach alpha of the total score of 0.90 [28]. Translated with permission of Drotar. FBII has been previously used in studies of children with ABI [21,29]. We will use the total intensity raw score for the analysis.

**Parent depressive symptoms.** Beck's Depression Inventory (IDB) [30] is used to measure parent's depressive symptoms. Depressive symptoms are categorized depending on their intensity in four levels (normal, mild, moderate, severe).

**Parent's anxiety symptoms.** Inventory Anxiety State Trait (IAST) [31] is a Likert questionnaire that measures anxiety symptoms in adults. The state scale which measures the anxiety symptoms experienced at the moment was used. Based in the intensity of the symptoms, anxiety is categorized in three levels (low, medium or high).

**Parent SR.** The Behavior Rating Inventory of Executive Function Adult Self-report (BRIEF-A) [32] is used to assess caregivers' self-regulation. T scores of the Global Executive Composite (GEC; Mean 50; SD 10) are used for the analyses. Scores  $\geq 65$  indicate clinically significant dysfunction.

#### 3.9.2. Parent outcomes

**Parent stress.** Parent Stress Index (PSI) short form [33] is used to measure parental stress, using the Total Stress T score (Mean 50; SD 10). This scale reflects the level of parental stress experienced by the respondent. Scores  $\geq 65$  indicate a high level of parental stress.

**Parenting practices.** The Parenting Scale (PS) [34] is used to assess parenting practices. This scale measures disciplinary practices associated with problematic behavior in the child [34]. We used the version translated to Spanish with permission of the first author David Arnold. The mean of the total scale raw score is used for the analysis. Total mean scores  $\geq 3.2$  represent clinically dysfunctional levels of disciplinary practices [35,36].

**Parent self-efficacy.** Parent self-efficacy is assessed using the parenting sense of competence scale (PSOC) [37]. PSOC is a parent self-report commonly used to measure parental self-efficacy [38]. In this study we use the Spanish version of PSOC which consists of 10 items [39]. The Spanish version PSOC address perceived effectiveness as parent and parental controllability to educational tasks. For the analysis we use the means of two subscales (1) perceived effectiveness as parent and (2) parental controllability.

#### 3.9.3. Child characteristics

Child demographics such as age, time since injury, main concern of

the parents and main concern at school is obtained during the first interview with the caregiver.

Intellectual ability. Full Scale IQ score (Mean 100; SD 15) is obtained using a combination proposed by Sattler (2010) of 5 subtests of the Wechsler Intelligence Scale for Children WISC-IV- [40] using Mexican norms.

Severity of the lesion. ABI severity is determined using the criteria described by Woods, Catroppa [36]. Brain injury is classified as mild with a Glasgow Coma Scale (GCS) 13–15, no evidence of mass lesion on Computed Tomography (CT) or Magnetic resonance imaging (MRI) and no neurological deficits; Moderate GCS 9–12, and/or mass lesion or other evidence of specific injury on CT/MRI and/or neurological impairment; and severe GCS 3–8, mass lesion or other evidence of specific injury on CT/MRI and/or neurological impairment.

### 3.9.4. Child outcomes

Child behavior at home. Eyberg Child Behavior Inventory (ECBI) [41] and the Child Behavior Checklist (CBCL) [42] parent form. The intensity and Problem T scores (Mean 50; SD 10) from the ECBI are used for the analysis. The intensity scale measures frequency of difficult behavior. Scores of  $\geq 60$  for this scale reflects severe behavior problems identified by parents [41]. The problem scale measures whether the parent considers the behavior a problem or not, scores of  $\geq 60$  identify parents which are significantly bothered by their child's behavior problems [41]. The total scale score from the CBCL parent form [42] is also completed. The total score encompasses items from the syndrome scales ( $M = 50$ ,  $SD = 10$ ) with  $\geq 63$  indicating dysfunction.

Child behavior at school. The Sutter-Eyberg Student Behavior Inventory-Revised (SESBI) [41] and the Teacher Report Form (TRF) [42]. The version translated to Latin American Spanish from the TRF from ASEBA is used with permission License 1294-02-12-16. The total score of the TRF is used in the analysis. The total score encompasses items from the syndrome scales [42]. Scores of  $\geq 63$  indicate dysfunction [42].

Cognitive SR. 1) Metacognition Index (MI; Mean 50; SD 10) from the Behavior Rating Inventory of Executive Function parent form (BRIEF) [43], measures child's ability to self-manage tasks. Scores  $\geq 65$  are considered abnormal [43]. 2) Test of Everyday Attention for Children Second Edition (TEA-Ch 2) [44]: Balloon-hunt and the Hide and seek (5–8 years) or Hector cancellation and Hecuba visual search ( $> 8$  years) and 3) Impulsivity: Matching Familiar Figure Test (MFFT) [45]: Impulsivity score (Mean 0, SD 1),  $\geq 1$  indicate a high level of impulsivity.

Emotional SR. 1) BRIEF parent form [43] emotional control (EC; Mean 50; SD 10); and 2) Emotion Regulation Checklist (ERCL) [46] a 24-item questionnaire rated on a 4-point Likert scale indicating the frequency of behaviors. We are using the Spanish version done by Farina, Maldonado-Morales and Murillo-Chavez (2013) with permission of Dante Cicchetti. The ERCL gives two subscales: i) emotion regulation and ii) negativity-lability. Increased scores in the emotion regulation scale indicate improvement in emotion SR, whereas increased scores in the negativity-lability scale indicate a decrease in emotion SR ability. Raw scores from both subscales are used for the analysis.

Behavioral SR. 1) Behavior Regulation Index (BRI) from the BRIEF-parent form [43] (Mean 50, SD 10) and 2) 10-min Delay Gratification Task (DGT) [47]. In the DGT the child receives an unwrapped chocolate. The child is subsequently asked to wait alone for 10 min in a room with no distractors in order to receive a second chocolate. There is a bell in the room which the child can ring in case he wants the assessor to return. The behavior is rated from 1 to 4 points. Children who remain in their seat get 1 point, children who stood-up from their seat get 2 points, children who touch the chocolate get 3 points and children who eat the chocolate or ring the bell before the 10-min wait receive 4 points. This score is used for the analysis, where higher score reflects poorer behavior regulation. The behavior is analyzed on videos

recorded with a hidden camera while the assessor left the office. The BRI measures the child's ability to modulate behavior [43]. Scores  $\geq 65$  indicate dysfunction [43].

### 3.9.5. Feasibility

The feasibility of the intervention is measured with the percentage of sessions attended and the total raw score of the Abbreviated Acceptability Rating Profile-Parenting (AARP) [48] with permission of Elsevier. The AARP consists of 8 items that are rated on a Likert scale from 1 to 6. The maximum score is 48. Higher scores indicate more acceptability. In addition, the parents are invited to write a comment about their opinion of the program.

### 3.10. Data management

The data are collected in the form of standardized parent and teacher reported questionnaires, and neuropsychological assessments are stored in locked facilities with restricted access where the main researcher determines eligibility for access as outlined in the ethics. The data collected are entered onto a password protected study database by study staff and are identifiable by a unique study identification number. Identifiable data, such as names and contact details, are kept in a separate file which can only be accessed by certain study staff (i.e. project coordinator, research assistant). The information collected from this study is only available to those involved in this study. In the event that parents request that certain study information or study reports to be provided to a third party (i.e. pediatrician, school teacher, family member), a Permission to Share Information form is completed and sign by the parents to allow study information to be released and shared. All staff and researchers that are working on this study are trained in matters of confidentiality. The information collected as part of this study will be retained until the youngest participant turns 25, unless further follow-up of the cohort is planned as per ethics requirements.

### 3.11. Sample size

Sample size calculations were based on the ability to detect a statistically significant difference of 0.8 SD ( $H_0$ : difference = 0) between the two treatment arms based on the externalizing index of CBCL (8 points), with a significance level of 0.05 and power of 0.80. Therefore, 26 participants are required per group. Allowing for an estimated 20% lost to follow-up, we therefore aim to recruit a total of 66 participants, which will be randomized across the two arms (33 per arm).

### 3.12. Statistical analysis

Participant data, attrition and outcome measures will be presented using descriptive statistics. To determine the sample's representativeness participants will be compared to non-participants based on the inclusion and exclusion criteria. Baselines characteristics of the participants who completed the follow-up assessment will be compared with the characteristics of the participants who drop out. Detailed descriptive analysis of pre-intervention child, parent and family characteristics will also be conducted to thoroughly explore the characteristics of families enrolled. We will compare the group characteristics of both groups at pre-assessment and if we find significant differences in any variable we will do statistical control using it as a co-variable. Comparisons of continuous measures will be made using independent samples *t*-test or Mann-Whitney U tests (depending on the distributions of the samples). Chi squared tests or Fisher's exact test will carry out between-group comparison of categorical variables.

Intervention efficacy will be assessed by comparisons between pre-intervention, post and follow up in each group. We will also compare the outcomes of the Signposts group and the CG at post intervention (T3) and Follow-up (T4) using independent *t*-tests, or its non-parametric equivalent depending on the distribution of the samples.

Potential confounds (e.g., social risk) and moderators (e.g., child age, time since injury) will be explored. As secondary analysis linear regressions will be completed to identify the impact that parent characteristics have on the intervention outcomes. Both completed and intention-to-treat analyses will be conducted. For those with incomplete data sets, multiple imputation will be explored and applied where the statistical assumptions are met. To reduce the probability of Type I error a false discovery rate adjustment will be applied. A significance level of 0.05 will be employed for all analyses.

#### 4. Discussion

The study describes the research protocol of a parenting intervention compared to telephone support for Mexican parents of children with ABI. This protocol paper explains the consequences of early onset of ABI and the importance of an intervention with a Mexican population. This protocol aims to investigate the effectiveness of an evidenced-based parenting program in improving child behavior, child SR, parenting practices, parenting sense of competence and reducing parenting stress compared to telephone support with a Mexican population. The design for this study is a blind Randomized Controlled Trial in order to provide a high level of evidence. Often, interventions are compared to care as usual, however comparison to telephone support will control for interaction with a clinician. In addition, having a comparison group allows us to control for spontaneous recovery that occurs after brain injury. Furthermore, we have measures completed by parents and teachers, as well as and tasks performed by the child, allowing us to examine whether any changes in behavior are transferred to the school environment.

To our knowledge this is the first study to examine the effectiveness of a parenting program for parents of children with ABI in a Hispanic population [21], however that study did not include a comparison group, nor child and teacher measures. This study will evaluate the feasibility and effectiveness of the translated Spanish version of Signposts for Mexican parents of children with ABI.

#### Trial status

The first participant was included in March 2016. The planned closing date is April 2017. Registered on March 8, 2017 in the Australian New Zealand Clinical Trials Registry identifier ACTRN12617000360314.

#### Ethics approval and consent to participate

The University of Melbourne Human Research Ethics Subcommittee approved the study protocol (1545487.1). The consent signed by the participants are in the additional files.

#### Competing interests

The authors declare no conflict of interests.

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#### Authors contributions

All authors made substantial contributions to this study and manuscript. CLCA participated in the design and coordination of the

study, recruitment, performed data collection, statistical analysis and wrote the manuscript. CC: participated in the design and coordination of the study and edited the manuscript. SH: participated in the statistical analysis and edited the manuscript. GYT: participated in the design and coordination of the study, recruitment and helped to edit the manuscript. BPC: participated in the design of the study, recruitment and helped to edit the manuscript. MAL: participated in the design and coordination of the study, recruitment and helped to edit the manuscript. AG: participated in the recruitment, performed data collection and helped to edit the manuscript. LSL: participated in the recruitment, data collection and helped to edit the manuscript; VA: participated in the design and coordination of the study and edited the manuscript. All the authors read the final draft of the manuscript.

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