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Outcomes and process evaluation of a program integrating physical activity into the primary school mathematics curriculum: The EASY Minds pilot randomized controlled trial.

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Figures 1
ABSTRACT

Objectives: This study evaluated the feasibility of the ‘Encouraging Activity to Stimulate Young (EASY) Minds’ program, a school-based intervention for integrating physical activity (PA) into mathematics lessons.

Design: randomized controlled trial

Methods: Two classes from a single school (n=54) were randomised to receive either the 6-week EASY Minds intervention (n=27) or follow their usual school program (n=27). The intervention involved the embedding of PA across the pre-existing mathematics program for three x 60 minute sessions per week. Changes in PA were measured using accelerometers and ‘on task’ behaviour was measured using momentary time sampling observation.

Results: Using intention-to-treat analysis, significant intervention effects were found for MVPA (9.7%, 95%CI=7.6, 11.8, p=<0.001) and sedentary time (-22.4%, CI=-24.9,-12.2, p≤0.001) for the intervention group during Mathematics lessons (9.30am-10.30am). Significant intervention effects were also shown for MVPA 8.7% (95% CI=5.8, 11.6, p=<0.001 and sedentary time -18.6% (95% CI=-24.9,-12.2, p=<0.001) across the whole school day. Furthermore, children displayed significantly greater ‘on-task’ behaviour across the intervention period with a 19.9% (95%C=2.4, 37.4, p=<0.03) mean difference between groups.

Conclusions: The EASY Minds program demonstrated that integrating movement across the primary mathematics syllabus is feasible and efficacious in enhancing school based-PA and improving on-task behaviour in mathematics lessons.

Key Words: physical activity, on task behaviour, integration, mathematics, primary school
1. Introduction

Multiple physical and psychological health benefits can be attained when children participate in the recommended levels of physical activity (PA)\(^1\). Worldwide, the proportion of young people meeting PA guidelines of 60 minutes per day of moderate-to-vigorous (MVPA) or health enhancing PA is less than 20%\(^2\). While schools are in a unique position to promote health enhancing PA, children’s time at school is commonly characterised by prolonged bouts of sitting\(^3\) and poorly taught Physical Education (PE), lessons that involve low levels of activity\(^4\). Emerging research also indicates that reducing sedentary behaviour may improve the health of children and, therefore, reducing sitting time across the school day should be a health priority\(^5\).

Increased concern over a crowded school curriculum has reduced PA throughout the school day. In addition, as standardised testing and school accountability increases, PE and PA in general, have become increasingly marginalised as numeracy and literacy targets become a dominant focus in many schools. PE represents one of the key opportunities to develop positive attitudes to PA and teach students the knowledge and skills to lead active lifestyles, significant barriers exist to quality PE in the primary school\(^6\)-\(^8\). Barriers identified are both teacher-related and institutional\(^6\). Furthermore, activity levels in PE are often very low\(^4\) and it has been suggested that children do not compensate for reduced PA throughout the school day by increasing PA outside school hours.

As such, other innovative strategies are required to engage students in PA and overcome some of the barriers inherent in curriculum-based approaches to PA promotion. One such recommendation, is to embrace classroom-based PA and promote PA across the curriculum as part of a whole-school approach to PA promotion\(^9\).

Indeed, the benefits of integrating PA may extend beyond students realising the health benefits of increased physical activity\(^10\). For example, emerging research suggests that movement aids learning and that the integration of PA across the curriculum may actually enhance learning in other curriculum areas\(^10\). There is an increasing body of literature that is focussing on the association
between PA and academic performance and provides evidence that physical activity enhances children’s cognitive functioning, concentration and on-task behaviour. Several studies have revealed children who are more physically active tend to perform better academically, that children who are physically active and fit are likely to have stronger academic performance and activity breaks can improve cognitive performance and classroom behaviour.

Previous classroom-based physical activity interventions have found that the benefits of integrating PA during the school day include both increased total PA for students and positive learning outcomes. A number of studies have evaluated the effects of integrating PA across the primary curriculum to assist the learning process. The Take 10 program has been disseminated to more than 40,000 classrooms in the United States and replicated in both China and the UK. These studies have utilised short 10 minute bouts of PA (originally known as energisers) and have subsequently been used to reinforce previously taught academic concepts. It may well be that this approach actually intensifies the crowded curriculum issue and places further strain on academic instruction time or teachers may believe that these energisers are in fact a substitute for regular PE. “Texas I can” have developed physically active lessons that fully integrate PA. However, these studies have used pedometer steps as a measure of PA levels and therefore actual intensity of PA has not been examined. One recent study has focussed on PA integration and maths with promising results but the authors recognised the need that future studies need to use a control group to serve as a comparison.

Erwin’s et al recent review strongly recommends that more research on the effect of classroom-based physical activity interventions on both physical activity and learning and health outcomes is warranted as PA integration can potentially be an inexpensive and effective intervention for improving both learning and health outcomes for all learners.

Of the limited number of truly PA-integrated curriculum-based interventions, where activity has been used to teach or reinforce academic concepts in primary schools, none to our knowledge, have reported time spent in MVPA across the school day in a specific subject area, e.g., mathematics and reported on-task behaviour. Therefore, the aim of this unique study was to assess the feasibility and
preliminary efficacy of the Encouraging Activity to Stimulate Young (EASY) Minds program that involved the embedding of PA and reduction in sitting time across the pre-existing mathematics program.

2. Methods

Study approval was sought and obtained from the University of Newcastle Research Ethics Committee, Newcastle and Maitland Catholic Schools Diocese and the school Principal from one independent primary school in Newcastle, New South Wales (NSW), Australia. Information leaflets, parental and participant consent forms were sent home with students and those who returned signed consent forms were permitted to participate in the study.

The study design involved a randomized controlled trial (RCT) and the two classes were assigned to either the EASY Minds intervention or a wait list control group. The design, conduct and reporting of the EASY minds program will adhere to the Consolidation Standards of Reporting Trials (CONSORT) guidelines. Two classes of Years 5 and 6 students from one primary school were recruited. A randomization envelope was prepared and a blinded independent third party allocated the two classes into one of the two groups. Randomization by class was completed before baseline assessments in February 2012.

The EASY Minds program involved the integration of PA within mathematics for Stage 3 children. Stage 3 is the last two years (Years 5 and 6) of the Australian primary school education system (ages 10-12y). The program ran for 6-weeks with 3 x 60 minute lessons per week, taught by a member of the research team (NR) who was a qualified primary/PE teacher with 21 years’ experience.

Movement-based learning experiences were embedded in Mathematics lessons on three occasions per week over the six week period (Table 1 provides example activities). Movement was used to both explicitly teach and reinforce mathematic concepts. The researcher used the class teachers existing Mathematics program. No rewards were offered for participating in the study. Specific outcomes for Mathematics from the NSW Board of Studies syllabi were addressed in the program. The primary outcome was children’s school-based MVPA levels. Actigraph accelerometers (GT3X, Pensacola,
USA) were used to provide an objective measure of both PA intensity and duration. The Actigraph accelerometer has acceptable reliability and validity in both children and adolescents.\(^\text{19}\)

Accelerometers were worn Monday through to Thursday, during school hours only (09.00-15.00). The classroom teachers were responsible for distributing and collecting the accelerometers on a daily basis. Accelerometers were attached to an adjustable elastic belt and worn on the right hip. Raw data from the accelerometer were screened and analysed using Meter plus software version 4.7. Participants’ PA was included for analysis if they wore the accelerometer for at least five school hours on any given day. Similarly, students were only included in the analysis if they wore the accelerometer for 50 minutes of the 9.30-10.30 intervention period. Evenson cut points were used to classify activity as sedentary, light, moderate, vigorous or moderate-to-vigorous physical activity (MVPA).\(^\text{20}\) Data were collected in 15 second epochs and non-wear time was defined as 20 minutes of consecutive zeros. Height and weight were measured at baseline only to profile the sample. Weight was measured without shoes using a portable digital scale (Seca 770, Wedderburn) to the nearest 0.1kg and height was measured to the nearest 0.1 cm using a portable stadiometer (Design No. 1013522, Surgical and Medical Products, Seven Hills, Australia).

On task behaviour was included as a secondary outcome. Children’s on-task behaviour was observed using a momentary time sampling procedure. On-task behaviour was measured at baseline, midpoint (3 weeks) and post-test (6 weeks). Six students per class group were selected at random, using random statistical number tables and observed at 15 second intervals on a rotational basis over a 30 minute period in the allocated 9.30-10.30 time slot. Two trained research assistant observers observed simultaneously. This method of systematic observation has been recommended when seeking to simply describe the classroom behaviour of children.\(^\text{21}\) The assessors were blinded to the study hypothesis at baseline only. “On-task behaviour included behaviour that could be categorised as being ‘actively engaged’ or ‘passively engaged’. Actively engaged referred to a child being actively engaged in academic responding, e.g. reading, writing, performing a set task. Passively engaged was
categorised as behaviour where the child was listening to the teacher or a fellow student but was not actively participating in a set task. Off-task behaviour included behaviour that can be described as being either off-task motor, where a child moved in a manner not associated with the task (e.g. walking around the class), off-task verbal including off task verbal discussion or off task passive where a child was non-engaged but passive (e.g. staring into space). Momentary time sampling involves a category being assigned at a pre-determined set time, not over a time period. Observers listened to an electronic metronome via an ear piece that alerted them to observe and categorise a student’s behaviour every 15 seconds.

Research assistants received 2 hours of training focussing on identifying and classifying behaviour into the appropriate categories and undertook a pre-trial practice in the school to develop a consistent understanding of the categories. Following all observations, the observers compared notes to clarify discrepancies. Classroom behaviour was reported as a percentage of time and for this trial categorised as simply ‘on’ or ‘off task’.

The overall feasibility of the program was evaluated using the following metrics: successful recruitment of participants, study retention and process evaluation questionnaires exploring program satisfaction completed by both participating teachers and student participants. The questionnaire (available on request) included items focussed upon program timing (3 items), instructor quality (4 items), appropriateness of program content (4 items) and program impact (8 items). The questions used a 5 point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree).

The analyses were performed using IBM SPSS Statistics version 20 and all variables were checked for plausibility and missing values. Data are presented as mean (SD) for continuous variables and counts (percentages) for categorical variables. Linear mixed models were used to assess all outcomes for the impact of group (EASY Minds vs. control), time (treated as categorical with levels at baseline, 3 and 6 weeks) and the group-by-time interaction, with these three terms forming the base model. Mixed models are robust to the biases of missing data and provide appropriate balance of Type 1 and Type 2 errors. Mixed model analyses are consistent with the intention-to-treat
principle, assuming the data are missing at random \(^{22}\). Participant age and sex were examined as potential covariates in each model and any significant effects were adjusted for in the analyses. For each significant covariate, two-way interactions with time and treatment were also examined and, if significant, these effects were also controlled for.

3. Results

A total of 58 students were given information statements and consent forms. Fifty four children from Grade 5 and 6 (28 male and 26 female) were recruited with a mean age of 10.53 (+.7) years. No children were diagnosed with learning difficulties or developmental conditions.

At baseline, 52 students completed height and weight assessments, accelerometers were worn by 54 participants and 12 students were observed for on-task behaviour. Following baseline assessments, the two participating classes were randomised into the intervention or control groups. The intervention group consisted of 27 students (14 male, 13 female) and the control group consisted of 27 participants (14 male, 13 female).

The mean age and height of the participants was 10.5 (+0.7) years and 146.3(+8.1) cm, respectively. At baseline, the control class was more physically active in terms of MVPA (10.2%, +5.4) compared to the intervention group (6.4%, +2.5) across the school day. Of note however, the intervention group (2.5%, +1.4 MVPA) were more active during the 9.30-10.30 mathematics timeslot than the control group (1.1%+1.2%). The intervention group spent 82% (+4.4%) of mathematics in sedentary behaviour and the control group 76% (+9.3). At baseline on task behaviour was recorded as 70% (+13.0) for the control group and 60% % (+11.5) for the intervention group. Significant group by time effects favouring the intervention group were found for MVPA across both the 9.30-10.30 teaching timeslot (+9.7%, 95%CI 7.6, 11.8) and the school day (+8.7%, 95%CI 5.8, 11.6) from baseline to 6 weeks. Similar group by time effects were also found for sedentary behaviour in the teaching timeslot (-22.4%, 95%CI -27.3, -17.6) and the school day (-18.6%, 95%CI-24.9, -12.2), which also favoured the intervention group. A significant treatment effect was found for on-task behaviour from baseline
to 6 weeks (p=<0.001). During the intervention lessons (9.30-10.30) a 19.9% mean difference between groups in on-task behaviour was observed (Table 2).

Scores on the evaluation survey completed by the 27 students in the intervention group ranged from 4.0 to 4.9 out of 5 for the 20 items indicating high to very high satisfaction rates for the EASY Minds program. Students found the program highly enjoyable, (mean score=4.6 ± 0.7), enjoyed working outside the classroom (4.9 ± 0.3), and incorporating PA into their lessons (4.7 ± 0.5). The classroom teachers who observed every session completed the teacher evaluation of the program. This revealed high satisfaction with both the program (4.9 ± 0.1) and its impact (4.5 ± 0.2). These positive teacher findings are consistent with other classroom-based PA interventions. Both classroom teachers answered “strongly agree “when asked if they would feel comfortable teaching the program. Classroom teachers believed the program was well received by children, due to the inclusion of the physical activity and the promotion of group tasks. 17 of the 18 sessions were completed as intended. The classroom teacher observed all sessions to ensure the mathematical content was covered appropriately. This was through open dialogue between the researcher and class teachers. One session was missed due to the children all attending a religious festival.

4. Discussion

The primary aim of this study was to evaluate the feasibility and preliminary efficacy of a movement-based mathematics program in the primary school. The EASY Minds program resulted in significant intervention effects for MVPA during mathematics lessons and across the school day. In addition, there was a significant intervention effect for reduced sedentary time in mathematics lessons and across the school day and in “on-task” behaviours. The EASY Minds program was also well received and enjoyed by teachers and students.

The increased levels of MVPA and reduced sedentary time found among children in the EASY Minds program demonstrates the potential behavioural impact of this approach and is consistent with the findings of previous studies that have integrated PA in the primary classroom. However,
previous studies have not necessarily reported PA as MVPA, but have used step counts from
pedometers as their outcome and thus not been able to determine engagement in physical activity of
intensity that is considered health enhancing and makes comparison problematic. Those studies that
have used accelerometers have only reported MVPA and not sedentary time. Others have used
accelerometers with only a sub sample of the study group and not the whole group.

The EASY Minds program resulted in a significant increase in MVPA across the school day, not just
total PA (as measured by steps or counts per minute), suggesting that the integration of PA in the
school curriculum can help contribute to young people meeting current PA recommendations (i.e., 60
min/day of MVPA). As part of a multi-level intervention, a small increase of 6 minutes MVPA
during class time could have important clinical significance. It is extensively recognised that regular
PA has multiple benefits for physical, mental and cognitive health. Meeting the recommended
guidelines of 60 minutes MVPA per day is related to greater muscular strength, stronger bones, and
improved cardiovascular health, as well as reducing and preventing conditions such as anxiety,
depression and enhancing self-esteem. Additionally there is increasing evidence on the relationship
between MVPA and the structure and functioning of the brain. In this study we found that students
at baseline spent 66% of their school day and 79% of typical academic instruction time in sedentary
activity. It is worth noting that the intervention also reduced this sedentary behaviour. The evidence
on the health and developmental effects of reducing sedentary behaviour in children is currently
inconsistent, but these changes and the corresponding increases in light physical activity might
contribute to increased energy expenditure and obesity prevention, metabolic health, and
cognitive functioning. Therefore reducing sedentary behaviour across the school day especially for
children who won’t meet the current recommendations for MVPA may have physiological and
academic benefits.

On task behaviour has been shown to be a key predictor of academic success. Similar to previous
studies, EASY Minds demonstrated a significant improvement in ‘on task’ behaviour and thus
movement-based learning may potentially result in increased time on task. It is important to highlight
that time on task is time spent engaged in academic learning not simply time spent “behaving”. Future
investigations need to determine if increased on task behaviour is a result of the PA alone or the innovative approach to learning28.

The strengths of the EASY Minds feasibility study are that it is an innovative and unique program that specifically integrates PA across the primary school mathematics curriculum. Importantly, the integrity of the mathematics lesson outcomes was maintained throughout. The study used trained assessors and observers for all assessments and observations. Clearly an additional benefit to school-based curriculum interventions is that unless a child leaves the school they remain in the study for its full duration, as such retention rates are expectedly high. The use of objectively measured PA via accelerometry is a further strength of the study.

There are some major limitations that should be noted. Whilst the results of the study are very positive, it is worth noting that the program was delivered by the researcher, a HPE trained specialist, with extensive experience in the primary classroom. Further studies will need to evaluate the effectiveness of classroom teachers in delivering the program to assess both the sustainability and useability of the program in the school setting. It may well be that the single biggest barrier to PA integration will be teachers own beliefs, perceptions and attitude towards PA39 and it has been shown that social support provided by the classroom teacher mediates changes in children’s PA behaviours30. It would therefore appear imperative that teachers are involved in the planning phase of subsequent studies. Indeed a recent systematic review has highlighted the need for teachers to act as agents of change and to be involved in the delivery of subsequent programs to improve the cost effectiveness, sustainability and feasibility of programs 15. A key part of this will need to be professional learning focussing on up skilling teachers in working outside the classroom. Although results were significant for on task behaviour, the results are limited by the small sample size and assessors only being blinded at baseline. This may have influenced the findings. Similarly, it is possible that factors outside the intervention may have been responsible for the decrease in MVPA among participants in the control group at 3 and 6 weeks across the school day. Despite this being a group RCT, the intervention was carried out in a single school and the analysis could not take into
account clustering. Whilst the authors cannot be sure as to why there was such a significant drop in the PA levels of the control group, it is worth noting that the control group were preparing for standardised national tests, unlike the intervention group. This may or may not have influenced the classroom teacher’s willingness to provide children with opportunities to be physically active throughout the school day.

5. Conclusions

PE programs alone cannot solely achieve the goal of increasing children’s PA levels. The EASY Minds program was successful in improving MVPA, reducing sedentary time and increasing on task behaviour. Our findings illustrate the potential of movement-based learning in the primary school setting. This successful feasibility will be used to inform a larger RCT to determine the effect and translation of EASY minds.

Practical Implications

Integrating PA led to increased MVPA within the mathematics lesson and the school day
Integrating PA led to a reduction in sedentary behaviour within the mathematics lesson and the school day
Integrating PA in mathematics led to an increase in on task behaviour

Human Subjects Approval Statement

This study protocol was approved by the human ethics committee at the University of Newcastle, Australia.

Acknowledgements

The authors would like to thank the participants for the time and effort given to this study.

References


### Table 1 Example activities used in the EASY Minds program

<table>
<thead>
<tr>
<th>Academic concepts</th>
<th>Description of activity</th>
</tr>
</thead>
</table>
| Recall multiplication facts | • Students performed a modified version of the popular dance “Macarena” whilst recalling mathematics facts. This involved crossing the right hand to left shoulder, left hand to right shoulder, right hand to left hip and left hand to right hip whilst recalling number facts.  
• Students performed slap count whilst recalling mathematics facts. This involved students facing a partner and taking turns to place their right hand on the palm of their partner’s right hand and then their left hand in their partner’s left hand whilst recalling number facts.  
• Drill ladders- students used a variety of footwork patterns and recalled multiplication facts whilst stepping in each rung. |
| Multiple choice Algorithms  | • Students were given an algorithm on the whiteboard with four possible answers.  
• Students responded to the answer by performing a set movement  
• E.g., Answer A= Tricep dips, B= Squats, C= March on spot |
<p>| Create line graphs          | • Students completed a 10 minute aerobic routine and recorded heart rates every minute (Heart Rate Monitor worn by several children). This information was then used to create a line graph. |</p>
<table>
<thead>
<tr>
<th>Activity</th>
<th>Description</th>
</tr>
</thead>
</table>
| Estimate distance                            | • Students estimated distances around the school. E.g., Classroom to office. They counted steps, recorded using a pedometer and checked using a trundle wheel.  
• Students threw, kicked and struck objects of different sizes. They then estimated and measured distances using tape measures.                                                                                                                                             |
| Use a digital stopwatch                      | • Students used a stopwatch and timed themselves over various short distances, 10, 20 m. They used this information to predict how long it would take to race 100m. This was used for a variety of locomotor movements.                                                                                                                         |
| Work out mode, mean and median               | • Students completed a tabloid of activities including, skipping, throw and catch, ball bouncing, shuttle runs over 30- second periods. The results of groups were compiled and students worked out means, modes and median values.                                                                                                                           |
| Solve mathematical equations                 | • Koosh balls were thrown on to a horizontal target mat of concentric circles with a score value. The total score was then multiplied by the number rolled on a 20 sided dice.                                                                                                                                   |
Table 2. Changes in outcome variables by treatment group from baseline to 3 weeks and baseline to 6 weeks and differences in outcomes among the treatment groups at 6 weeks (ITT analysis) (n = 54)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Week</th>
<th>Treatment group</th>
<th>Mean change from baseline (95% CI)</th>
<th>Mean difference between groups (95% CI)</th>
<th>Group x time P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Control (n = 27)</td>
<td>Easy Minds (n = 27)</td>
<td>Control vs. Easy Minds (95% CI)</td>
<td></td>
</tr>
<tr>
<td>Sed %</td>
<td>3</td>
<td>6.6 (2.8, 10.3)</td>
<td>-0.7 (-4.4, 3.0)</td>
<td>-7.2 (-12.5, 2.0)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>4.7 (0.2, 9.3)</td>
<td>-13.9 (-18.3, -9.4)</td>
<td>-18.6 (-24.9, -12.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Light %</td>
<td>3</td>
<td>-1.4 (-4.2, 1.4)</td>
<td>-0.2 (-2.9, 2.6)</td>
<td>1.2 (-2.7, 5.1)</td>
<td>0.54</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>-2.0 (-5.4, 1.4)</td>
<td>10.9 (7.6, 14.2)</td>
<td>12.9 (8.2, 17.6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mod %</td>
<td>3</td>
<td>-2.4 (-3.4, -1.3)</td>
<td>-0.6 (-1.6, 0.5)</td>
<td>1.8 (0.3, 3.3)</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>-2.6 (-3.8, -1.4)</td>
<td>1.8 (0.6, 2.9)</td>
<td>4.3 (2.7, 6.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Vig %</td>
<td>3</td>
<td>-2.9 (-4.3, -1.5)</td>
<td>1.4 (-0.0, 2.8)</td>
<td>4.3 (2.3, 6.3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>-3.0 (-4.2, -1.9)</td>
<td>1.3 (0.1, 2.4)</td>
<td>4.3 (2.6, 5.9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>MVPA %</td>
<td>3</td>
<td>-5.3 (-7.3, -3.3)</td>
<td>0.8 (-1.2, 2.8)</td>
<td>6.1 (3.3, 8.9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>-5.7 (-7.7, -3.6)</td>
<td>3.0 (1.0, 5.0)</td>
<td>8.7 (5.8, 11.6)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

School day (9-00-3.00)

Mathematics class (9.30-10.30)

Abbreviations: CI, confidence interval; ITT, intention to treat; a adjusted for gender. b adjusted for sex x treatment interaction. c n = 51 d n = 12
Figure 1: Flow of participants through the study.

- Schools invited to participate (n=1)
- Teachers consented (n=3)
- Participants assessed for eligibility (n=58)
- Assessed for primary outcome at baseline (n=54)
- Declined to participate (n=4) No reasons given
- Randomisation by class
- EASY Minds Intervention 1 class (n=27)
  - Lost to follow up (n=0)
  - Analysed for Primary outcome (n=27)
- Wait-list control 1 class (n=27)
  - Lost to follow up (n=0)
  - Analysed for Primary outcome (n=27)