

Multi-stakeholders' attitudes and perceptions towards adopting an early autism intervention

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## Abstract

Research into caregiver-led, low-intensity interventions in low and middle-income countries needs to be explored so young children with Autism Spectrum Disorder (ASD) are given the opportunity to benefit from early intervention approaches. A pilot study to improve access to early intervention for autism in Africa has taken place to address this problem. The Early Start Denver Model (ESDM) informed caregiver coaching is an example of a caregiver-led intervention. In the pilot study, ESDM trained therapists train early childhood development (ECD) workers to coach caregivers of children with ASD in this intervention. This current study attempts to examine the implementation outcomes of multi-stakeholders' perceived acceptability, appropriateness and feasibility of the intervention. The Evidence-Based Practice Attitude Scale (EBPAS) was administered to ESDM trained therapists ( $n=3$ ), school supervisors ( $n=2$ ) and ECD workers ( $n=2$ ) pre-test and post-test. The Acceptability of Intervention Measure (AIM), The Intervention Appropriateness Measure (IAM), and The Feasibility of Intervention Measure (FIM) were administered after the intervention had been completed to the same participants as the EBPAS questionnaire but also included caregivers ( $n=2$ ). The EBPAS results were analysed to determine a significant difference between the two sets of scores. There was no statistical significance between pre-test and post-test scores. However, all participants showed favourable attitudes towards the intervention. From the AIM, IAM and FIM results, all participants had high levels of perceived acceptability, appropriateness and feasibility towards the intervention. This is an important finding that will assist the pilot project in assessing the success of the intervention.

*Keywords:* Autism Spectrum Disorder, caregiver-led intervention, early-intervention, evidence-based practice, implementation outcomes, non-specialist coaching

Autism Spectrum Disorder (ASD) is a neurodevelopmental disorder with symptoms that typically become apparent in infancy and early childhood (Dawson et al., 2009). ASD includes impairments in the domains of social communication and social interaction and restricted, repetitive patterns of behaviour, interests or activities (American Psychiatric Association, 2013). Additionally, research shows that approximately 70% of those diagnosed with ASD have at least one comorbid disorder (Simonoff et al., 2008). The global prevalence of ASD is estimated to be between 1-2% (Frieden, Jaffe, Cono, Richards, & Iademarco, 2014). With ASD contributing globally to the highest disability-adjusted life-years in comparison to other childhood-onset mental disorders, ASD intervention is essential (Baxter et al., 2015). Despite the fact that the majority of people with ASD live in low and middle-income countries (LMIC), ASD intervention development and research has predominantly occurred in high-income countries which means that contextual factors need to be taken into account in order to ensure that these interventions will be effective in LMICs (Guler, de Vries, Seris, Shabalala, & Franz, 2017). Additionally, many intervention programmes are intensive and costly (Lord et al., 2005). Intervention services in LMICs such as South Africa, are scarce and the services that are available are often overburdened (Malcolm-Smith, Hoogenhout, Ing, Thomas, & de Vries, 2013). In the Western Cape alone, there are over 500 applicants waitlisted for enrolment in specialised ASD schools (Guler et al., 2017). Therefore, research into caregiver-led, low-intensity interventions that do not rely on costly one-on-one intervention models needs to be explored in LMIC setting so young children with ASD are given the opportunity to benefit from early intervention approaches (Franz, Chambers, von Isenburg, & de Vries, 2017; Malcolm-Smith et al., 2013). An example of a caregiver-led intervention is the Parent Early Start Denver Model (P-ESDM) where parents are coached in intervention strategies that they can then integrate throughout the day in typical parent-child interactions, such as during toy play, meal and bath time (Estes et al.,

2014). Although EPBs such as P-ESDM have benefits such as improving cognitive and adaptive behaviour (Dawson et al., 2009), there has not been extensive implementation of such interventions (Vivanti et al., 2018). A possible reason for this is thought to be stakeholders' attitudes towards adopting EPBs as well as initial intervention implementation costs (Dingfelder & Mandell, 2011). The more research on implementation challenges, the better interventions can be moulded to fit the context in which they are needed (Vivanti et al., 2018). Despite stakeholders' attitude towards EPBs being of vital importance for the success of the implementation of EPBs, little literature exists on this topic globally (Aarons & Palinkas, 2007).

### **Early Intervention**

Literature on ASD intervention highlights the importance of early intervention to lessen long-term impairments and decrease long-term costs (Cidav et al., 2017). Intensive behavioural intervention of 15-25 hours per week is an initially expensive treatment of between \$40,000 to \$80,000 per year (Cidav et al., 2017). However, early intervention is valuable because important functioning such as communication and language skills, intellectual ability and adaptive behaviour progress with early intervention (Estes et al., 2015). Studies have shown that this improvement in behaviour and functioning is able to be sustained at least two years after the intervention (Estes et al., 2015). Although socio-economic factors, race or culture are not considered to contribute towards the prevalence of ASD, these factors do influence access to care in South Africa (Springer, Van Toorn, Laughton, & Kidd, 2013). For many children, participating in early intensive intervention is not possible unless family members can afford the expensive treatment themselves (Guler et al., 2017). Although early ASD intervention is expensive, it is thought to reduce the dependency on subsequent costs, and therefore reduce the financial cost of an individual diagnosed with ASD (Cidav et al., 2017). Reduced subsequent costs may be because

positive effects of early intervention on a child's outcomes reduce the need for other services such as speech therapy and other educational services or supports (Cidav et al., 2017).

Whilst financial benefits of an intervention are not the predominant interest in evaluating intervention impact, it is a necessary factor to consider. ASD diagnosis is a heavy financial burden. In South Africa, ASD services provided by the public health sector are very limited and overburdened and private sector services which require caregivers to pay for are unaffordable for are very costly (Guler et al., 2017). A shift towards caregiver led interventions has the potential to reduce dependency on other ASD intervention services and supports, alleviating caregiver financial burden (Drew et al., 2002). However, it is important to consider the costs of the provider who is training caregivers. While caregiver led interventions have the ability to empower caregivers, there are still expenses related to the provider's cost of training and supporting caregivers that need to be considered to ensure the feasibility of the model.

### **Early Start Denver Model**

The Early Start Denver Model (ESDM) is a Naturalistic Developmental Behavioural Intervention (NBDI) (Waddington, van der Meer, & Sigafos, 2016). NBDIs use behavioural strategies that are taught in a child's natural setting, and uses daily routines as natural learning opportunities. Additionally, NBDIs involve shared control of the learning process between the child and the therapist (Schreibman et al., 2015). NBDI is theoretically based on research that shows children learn the best when they are active participants in the learning process and if the context is meaningful to the child. Challenges of NBDIs include cost of high intensity implementation, training demands and intervention complexity (Schreibman et al., 2015). ESDM is an early behavioural intervention programme for children from the ages of 12-60 months and aims to improve functioning across multiple developmental domains (Rogers & Dawson, 2010). The location of the intervention can be the child's home

environment and the programme can be implemented by a combination of trained therapists, teachers and parents (Dawson et al., 2009). The belief that ASD disrupts development is at the core of the ESDM model. ESDM merges a relationship-focused developmental model with teaching practices of Applied Behavioural Analysis (ABA) (Dawson et al., 2009). As ASD affects multiple developmental domains, ESDM aims to address these developmental gaps by building on social communication using joint activity routines in object-based play, sensory social routines and daily routines (Rogers et al., 2012). ESDM can be delivered as a one-on-one therapist led intervention (Estes et al., 2015), a group-based intervention in a preschool setting (Vivanti, Duncan, Dawson, & Rogers, 2017), a parent delivered intervention (Rogers et al., 2012) or by use of telehealth (Vismara, McCormick, Young, Nadhan, & Monlux, 2013). A randomised control trial showed that after receiving intensive ESDM intervention for two years, participants on average showed an increased IQ score, cognitive ability, and improved expressive and receptive language which was sustained two years after the intervention ended (Estes et al., 2015). The location of treatment in the home environment or other naturalistic settings is important as it may assist in generalization of skills across child environments (Schreibman et al., 2015). Caregivers in a qualitative South African study reported that their favoured location for treatment was the home, for convenience as well as for being able to mould the intervention to fit into the child's natural surroundings and routines (Guler et al., 2017). From randomised clinical trials, ESDM participants' performance improved, despite significant reduction in one-on-one treatment, which authors note was a result of the children's access to early intervention which provided them with skills to learn from less rigid and more naturalistic settings (Estes et al., 2015)

Importantly, ESDM emphasises parental involvement (Dawson et al., 2009). Rogers et al. (2012) developed Parent Early Start Denver Model (P-ESDM) which is a parent-delivered intervention that concentrates on parental use of ESDM teaching strategies in play

and everyday tasks. Parental coaching in early intervention programmes is said to reduce problem behaviours and increase children's verbal and nonverbal communication skills (Rogers et al., 2012). Studies have shown that parents that participate in P-ESDM on average experience lower levels of parental stress than parents receiving community intervention (Estes et al., 2014). Parents coached in P-ESDM report a strong working alliance with their primary therapist which may influence parental attitudes towards the intervention programme (Rogers et al., 2012). Traditionally, the primary therapist is a highly experienced and qualified professional (Rogers et al., 2012). Issues associated with highly trained therapist-led intervention include the access to these trained therapists in some areas (Penner et al., 2015) as well as high levels of intensity (Vivanti et al., 2014). For example, with only three ESDM certified therapists in South Africa, a therapist-led intervention model is probably not feasible for as many children to receive ESDM intervention as possible. As many community settings lack access to financial and professional resources, a community adapted ESDM (C-ESDM) that utilises non-specialist community workers as parent-training coaches may be more appropriate (Einfeld et al., 2012). However, a more parent-based intervention model is not without its challenges, as greater demand of parental time due to coaching sessions and increased interaction time can have significant financial productivity costs for the caregiver (Cidav et al., 2017).

### **The Importance of Early Intervention Programme Research**

ASD early intervention programmes need to be expanded globally to reach communities, particularly those in LMICs like South Africa, where the treatment gap for ASD is almost 100%, so young children with ASD are given the opportunity to benefit from early intervention approaches (Rahman et al., 2016). Despite the majority of people with ASD living in LMICs, the development of interventions has predominantly taken place in high-income countries (Elsabbagh et al., 2012). Therefore, interventions may not have taken



context specific factors such as culture, language, treatment location, cost of treatment, parenting practices, and stigma into account which may impact on the utility of these interventions in LMICs (Guler et al., 2017). Sub-Saharan countries need to improve policies and increase service provision with regards to childhood development disorders (Olusanya et al., 2018). Majority of research and interventions for children in sub-Saharan Africa have centred on communicable diseases, namely, HIV/AIDS, Malaria and Tuberculosis resulting in reduced infant mortality. However, little research has been done on non-communicable diseases such as ASD (Franz et al., 2017). Globally, approximately 52.9 million children under the age of five have a developmental disability (Olusanya et al., 2018). Research shows that majority of children in LMIC do not have access interventions that address developmental disorders such as ASD. In order to reduce this treatment gap, research into caregiver led and non-specialist workers interventions needs to take place in LMICs (Patel, Kieling, Maulik, & Divan, 2013).

Therefore, it is critical that research focuses on ensuring that EBPs that are developed in high income countries are transferable to LMICs for sustainable community use (Vivanti et al., 2014). Intervention programs that are developed in highly controlled research studies cannot always be implemented in the same manner when used in community practice (Dingfelder & Mandell, 2011). Research that investigates the feasibility and the implementation processes of these interventions, such as ESDM, in community settings is vital to ensure that intervention is effective to recipients in different contexts.

### **Implementation Outcomes**

Parent-led interventions have not always been successful. For example, feedback from parents involved in a pilot randomised control trial of parent training intervention showed that parents struggled to implement the required activities at home because of other their other daily demands involving their other children or work schedules (Drew et al., 2002). It is

important to consider the elements of implementations that make it useable to recipients. Additionally, parents' attitudes towards an intervention will influence their commitment to its implementation (Solish & Perry, 2008). A way to examine participants' attitudes and perceptions of an intervention is through implementation outcomes. Proctor et al. (2011) define implementation outcomes as "the effects of deliberate and purposive actions to implement new treatments, practices, and services" (p. 65). Implementation outcomes are distinct from service systems outcomes and clinical treatment outcomes (Proctor et al., 2011) and are useful indicators of the implementation success (Weiner et al., 2017). As an intervention will not be effective if it is not implemented well, implementation outcomes serve as necessary preconditions for attaining desired changes in clinical or service outcomes. Therefore, indicators of implementation outcomes such as acceptability, appropriateness, feasibility, fidelity, cost, adoption, penetration and sustainability are of vital importance in implementation science (Weiner et al., 2017).

Although there has been an increase in ASD early intervention research in the last decade, research needs to be conducted to determine the effectiveness of the implementation of these interventions (Vivanti et al., 2017). The process of implementing EBPs, such as P-ESDM, is complex with many EBPs not reaching their full potential because of issues that occur during the implementation process (Aarons, Hurlburt, & Horwitz, 2011). EBPs refer to psychological interventions that have been proved through empirical evidence to successfully reduce symptoms and improve functioning of clients (Kagee & Lund, 2012). Many of the challenges are because these EBPs are delivered by both individuals and organisations that are influenced by complex, multi-faceted social contexts (Aarons et al., 2011). Barriers include lack of skills, knowledge and access to research, limited training period, training costs and stakeholders' attitude towards the EBP (Proctor et al., 2007). In addition, the organisational leadership and the commitment from staff or the 'buy in' of the professionals

are important issues to consider when implementing a new EBP. These are all factors that should be greatly taken into account during ASD research so that researchers can understand not only how an EBP is effective but to what extent it is viable in the intended context in which it is delivered (Vivanti et al., 2018).

Pilot studies tend to focus on intervention benefits and overlook the important information such as feasibility, acceptability and acceptance of the intervention by key stakeholders. This is an important step missing in determining intervention effectiveness (Vivanti et al., 2018).

### **Motivation For Research**

There has been a greater focus on ASD as a global public health concern (Khan et al., 2012), and as a result there has been an increasing number of NDBIs in community settings (Vivanti et al., 2018). There have been positive outcomes for children receiving community-based ESDM intervention for example in a community based ESDM trial conducted by Vivanti et al. (2014), children showed significant gains in developmental rates and receptive language development. As NDBIs focus on play and daily routines, cultural context greatly influences these interactions. The issue with a vast majority of NDBI research occurring within Western contexts is that research findings are not globally representative. Less than 3% of participants in child development research come from Central and South America, Africa, Asia and the Middle East, which are areas that contain approximately 85% of the world's population (Nielsen, Haun, Kärtner, & Legare, 2017). The lack of literature on NDBIs in LMICs highlights the critical need for ASD early intervention research in these contexts to ensure that interventions are culturally, economically and socially relevant (Guler et al., 2017). As there is a lack of specialist service providers, ASD treatment needs in LMICs are unlikely to be fulfilled by highly trained therapists (de Vries, 2016). With this being the case, caregiver and non-specialist delivered ASD intervention is a resource that has the

potential to provide children with ASD the benefits of early intervention (World Health Organisation, 2015). We need to explore the implementation of NDBIs using caregiver and non-specialist community workers in LMICs and in varied socio-economic contexts to ensure that the research which has taken place predominantly in Western settings is effective and feasible outside of this setting. Of particular concern during this process is to think about whether or not these intervention models are feasible, acceptable and appropriate in a LMIC, socio-economically diverse context such as South Africa. A way to examine these implementation outcomes is through the use of surveys completed by stakeholders during the implementation process (Proctor et al., 201).

### **Aims and Hypotheses**

Given the global prevalence rate of ASD and it contributing globally to the highest disability-adjusted life-years in comparison to other childhood-onset mental disorders (Baxter et al., 2015), research in ASD intervention should be prioritised. However, as mentioned, NDBIs when implemented intensely are costly (Schreibman et al., 2015). Therefore, low-intensity caregiver coaching interventions where caregivers are trained in ESDM techniques by non-specialist workers, has the potential to reduce the cost of using intensive interventions implemented by highly specialised professionals and provide caregivers with techniques to use in their everyday interaction with their young child with ASD. There will be task shifting of intervention skills to the caregiver as well as task shift caregiver coaching to non-specialists. In this study non-specialists are Early Childhood Development workers (ECD workers) who are employed by the Western Cape Department of Education. As noted, implementation outcomes are important to measure because if an intervention is not being properly implemented, it cannot be successful. Three important measures of implementation outcome are acceptability, appropriateness and feasibility (Proctor et al., 2011). Firstly, ‘acceptability’ is the perception of stakeholders that an intervention or treatment is seen as

being agreeable or satisfactory (Weiner et al., 2017). A poor level of acceptability is problematic for the implementation process (Proctor et al., 2011). The concept of acceptability also includes stakeholders' attitudes towards and intervention and its implementation (Aarons, 2005). In past research, these attitudes towards an intervention are said to improve after training (Beidas & Kendall, 2010). Secondly, 'appropriateness' is the perceived fit or relevance of an EBP in a given setting and assisting in a specific issue (Weiner et al., 2017). Appropriateness is important to see if there is any "pushback" to the implementation process as a result of stakeholders feeling the EBP is not in alignment with their expectations or current role (Proctor et al., 2011). Thirdly, 'feasibility' is the extent to which an EBP can be successfully implemented within a given setting (Weiner et al., 2017). Acceptability is believed to be a dynamic concept that has the ability to change. For this reason, perceived acceptability may vary before and after implementation so this measure is tested at pre-implementation and post-implementation. However, feasibility and appropriateness are best tested retrospectively so that stakeholders have experience to draw on to form their opinions of the implementation process of an intervention (Proctor et al., 2011). The scales used to measure some of these concepts have been so newly developed that there are yet to be any published studies using these scales. As this study is exploratory in nature, this does not pose too great of an issue. This study forms part of a joint project with the Department of Child and Adolescent Psychiatry (DCAP) and Duke University and is funded by the National Institute of Health in the United States (5K01MH104370-04). Dr. Franz (Duke University) is the Principal Investigator, and Prof de Vries (UCT) is the Co-Principal Investigator.

The principal research aim of this study is to measure multi-stakeholders' perceptions of the acceptability, appropriateness and feasibility of an evidence-based early autism intervention (P-ESDM) in South Africa.

I hypothesise that participants' attitudes towards implementing the intervention will change from pre-intervention to post-intervention. I expect that attitudes will become more favourable towards the use of EBPs after the intervention sessions as participants become more comfortable with the intervention. Due to the exploratory nature of the study, the retrospective manner in which the concepts can be tested, and the use of recently published scales, there is no a priori hypothesis with regards to the stakeholders' perceived feasibility and appropriateness of the intervention.

## **Method**

### **Setting**

The immediate setting of the study is the Department of Child and Adolescent Psychiatry (DCAP) headquarters, situated in Rosebank, Cape Town. This is where much of the intervention process took place. Although the Western Cape is seen as having better healthcare resources compared to other South African provinces, access to early ASD diagnosis and intervention services is still very limited for the majority of the population. An ASD diagnosis typically takes 9-18 months, or longer. Once a child has received a formal diagnosis from a tertiary hospital's neurodevelopmental clinic, their name is placed on the Western Cape Education Department Provincial ASD waiting list for placement at an ASD-specific school. Children are also referred for therapy which may consist of a 30 minute session from an occupational or speech therapist every four to six weeks. The onus of care for the child falls on the caregivers (Van Schalkwyk, Beyer, & de Vries, 2016). A study in 2016 showed 940 children with ASD were placed in Special Education Schools in the Western Cape Province but there were 744 children still on the waitlist (Pillay, Duncan, & de Vries, 2017). Of the nine ASD-specific schools in South Africa, six of the schools are in the Western Cape Province. With so few facilities to service the entire population, there are many children with ASD who are not able to attend these schools (Van Schalkwyk et al., 2016).

The private sector does have services available for children with ASD, but the quality of the services are inconsistent and expensive (Guler et al., 2017). South Africa has the greatest income inequality in the world (The World Banks, 2018) with the country's income inequality extending into the health sector resulting in great health inequality (Mayosi & Benatar, 2014). A paediatric clinic in the Western Cape saw that 94% of black African children with ASD were non-verbal at presentation, whilst only 42% of Caucasian children were non-verbal at presentation. The racial differences in verbal presentation during diagnosis were shown to be connected to socioeconomic factors that were barriers to care (Springer et al., 2013). This shows how socioeconomic factors influence inequality.

### **Design**

A caregiver coaching variation of ESDM is being adapted and piloted to be delivered by non-specialist workers. The first three ESDM therapists in Africa have been certified and two non-specialist ECD workers, who are employed by the Western Cape Department of Education at one of two schools that have learners diagnosed with ASD, have been trained. A South African adapted version of ESDM, to be delivered by non-specialists, uses Community ESDM (C-ESDM) caregiver education materials. These resources assist non-specialists to train parents to deliver P-ESDM (Rogers, Vismara, Dawson, & Stahmer, 2017). This is the larger study in which this project is embedded. This project provides information on the implementation outcomes, specifically the multi-stakeholders' perceived appropriateness, acceptability and feasibility of the intervention through a quantitative analysis. Multi-stakeholders include the caregivers of children with ASD, non-specialist ECD workers, school supervisors from ASD-specific schools and ESDM certified therapists. Data was gathered using four different questionnaires: The Acceptability of Intervention Measure (AIM) is a questionnaire that measures a stakeholder's perceived acceptability of an intervention. The Intervention Appropriateness Measure (IAM) is a questionnaire that

measures to what extent a stakeholder's perceives an intervention as being appropriate. The Feasibility of Intervention Measure (FIM) is a questionnaire that measures to what extent stakeholders' view an intervention as being feasible (Weiner et al., 2017). Each of these measures, the AIM, IAM and FIM, all separately assess a coaching and a video component of C-ESDM which will be described below.

The Evidence-Based Practice Attitude Scale (EBPAS) questionnaire was used to measure stakeholders' attitude towards P-ESDM (Aarons, 2004). Demographic data was collected prior to the intervention sessions. The caregivers received twelve, one hour sessions of P-ESDM coaching from non-specialist ECD workers where they were taught a new ESDM skill using a 'help is in your hands' video. The caregivers are then coached in the new skill by an ECD worker. This portion of the session includes live coaching and caregiver reflection as well as linking caregiver-child behaviours. The ECD workers were supervised by ESDM certified therapists during the intervention period.

Prior to the start of the caregiver coaching intervention, the EBPAS was administered to the ECD workers, school supervisors and ESD certified therapists. Following the twelve intervention sessions, the scale was re-administered. Caregivers did not complete this questionnaire as it has been developed to only assess intervention provider attitudes (Aarons, 2004).

The AIM, IAM and FIM were administered once at the end of the twelve caregiver coaching sessions because stakeholders needed experience with both components of the intervention, the caregiver coaching and C-ESDM 'help is in your hands', prior to completing these measures.

### **Participants**

Participants included three South Africa certified ESDM therapists who supervise the ECD workers, two ECD workers who are employed at autism schools in the Western Cape



Province, the two ECD workers school supervisors who are both head of departments at autism schools in the Western Cape Province, and two caregivers who received the caregiver coaching intervention. All participants were purposively sampled. See Appendix A for participants' demographic information.

**Inclusion criteria.** Three certified ESDM therapists, the only three in Africa, were included in the study. Inclusion criteria for ECD workers included working in one of the two schools described above. Inclusion criteria for school supervisor were being employed at one of the two schools described above. Inclusion criteria for caregivers included caring for a child aged between 18 and 72 months that has been diagnosed with ASD based on DSM-5 criteria by a developmental paediatrician. Additional inclusion criteria for caregivers: (1) speaks isiXhosa, Afrikaans or English; (2) lives within an area served by the Red Cross Neurodevelopmental clinic; and (3) is willing to participate in the intervention. Exclusion criteria for a caregiver was having a child ASD that has: (1) a neurodevelopmental disorder of known genetic aetiology; (2) significant sensory or motor impairment; (3) major physical problems; (4) uncontrolled seizures; (5) IQ below 35 as measured by mean age equivalence score on the Griffiths Scales of Mental Development; and (6) unable to attend three assessments and 12, one-hour, weekly consecutive intervention sessions.

## **Measures**

Of the identified implementation outcomes this study will focus on acceptability, appropriateness and feasibility as they are seen as the forerunners of indicators of implementation success. Additionally the indicators are simultaneously conceptually discrete, yet likely to be highly correlated which suggests that individual indicators may be seen as proxies for the other indicators (Weiner et al., 2017). Weiner et al. (2017) have recently developed three scales with four items that measure acceptability, appropriateness and feasibility. These three measures have been developed to be conducted as a group in order to

assess implementation outcomes of an intervention. These three scales have similar psychometric properties and layout.

**Acceptability.** The AIM is a four item scale developed by Weiner et al. (2017) in order to measure stakeholders' perceived sense of acceptability towards an implementation. Acceptability is defined as the extent to which a service, practice or treatment is seen as satisfactory or agreeable (Proctor et al., 2011). For the purpose of this study, the implementation is P-ESDM. Acceptability is believed to be based on personal values. Therefore, two individual's opinions of the same intervention may differ depending on their own preferences, needs or expectations (Proctor et al., 2011). The items require responses on a likert-scale which ranges from *completely disagree* to *completely agree* and have values ranging from 1-5 (Weiner et al., 2017). Higher scores indicate a greater sense of acceptability towards the intervention. The scale has a Flesch reading ease score of 95.15 which is a grade five reading level and there are no specialised skills or training needed to administer, score or analyse the scales (Weiner et al., 2017). This measure should not take longer than five minutes to complete and there is no cost involved in using the measure. The scale has good psychometric properties being both valid and reliable and has a Cronbach's alpha score of 0.85 (Weiner et al., 2017).

**Appropriateness.** The IAM measures stakeholders' perception of the appropriateness of an EBP, in this study being P-ESDM (Weiner et al., 2017). Appropriateness is defined as the extent to which stakeholders see an EBP as being compatible or relevant in the environment in which they would utilise the intervention and how it would assist a specific issue (Proctor et al., 2011). Although a similar construct to acceptability, appropriateness is distinct in that it is able to determine if there is any resistance in implementing an EBP by stakeholders. In this way, an intervention may be suitable for a particular issue but its features may make the intervention unacceptable to a stakeholder. This resistance may be because the

new EBP is seen as too greatly deviating from the original intervention method, the providers' skills or job position and expectations (Proctor et al., 2011). Like with the AIM, the IAM items require responses on a likert-scale which ranges from *completely disagree* to *completely agree* and have values ranging from 1-5 (Weiner et al., 2017). Higher scores indicate a greater sense of appropriateness towards the intervention. The scale has a Flesch reading ease score of 95.15 which is a grade five reading level and there are no specialised skills or training needed to administer, score or analyse the scales (Weiner et al., 2017). This measure should not take longer than five minutes to complete and there is no cost involved in using the measure. The scale's psychometric properties are strong with a Cronbach's alpha of 0.91, indicating excellent internal consistency, and is the highest score of the three scales developed by Weiner et al. (2017).

**Feasibility.** Weiner et al. (2017) developed the FIM to determine the extent to which a new treatment or innovation can be successfully carried out within a given setting. Again, feasibility is connected to the construct of appropriateness although on a conceptual level, they differ. For example, an intervention may be appropriate in that it is relevant in a given setting, but at the same time it may not be feasible because of access to resources such as funds or time (Proctor et al., 2011). Therefore, an intervention can be appropriate but not feasible and vice versa. Feasibility taps into the practical component of the intervention implementation, seeking to understand how easily the intervention can be implemented given the resources available and the context in which it will be delivered. As with the AIM and IAM, the FIM items require responses on a likert-scale which ranges from *completely disagree* to *completely agree* and have values ranging from 1-5 (Weiner et al., 2017). Higher scores indicate that participants believe the intervention to be more feasible. The scale has a Flesch reading ease score of 95.15 which is a grade five reading level and there are no specialised skills or training needed to administer, score or analyse the scales. This measure

should not take longer than five minutes to complete and there is no cost involved in using the measure. The Cronbach's alpha score for this four item scale is 0.89 which suggests the scale has good reliability (Weiner et al., 2017).

**Attitude.** Attitude is a subscale of the construct of acceptability (Aarons, 2017). It is important to the implementation process to understand stakeholders' attitudes towards an intervention as they can determine whether or not a stakeholder will try a new practice or not (Aarons, 2004). The EBPAS is a 15 item questionnaire that will be used to measure stakeholders' attitude towards P-ESDM (Aarons, 2004). Items require responses on a likert-scale which range from *Not at All* to *To a Very Great Extent*. While Aarons (2005) suggests using scoring values ranging from 0-4, for the purposes of this study the values ranged from 1-5 to ensure uniformity with the other measures. EBPAS provides information on four subscales of a participant's attitude towards EBPs as well as an overall scale scores (Aarons, McDonald, Sheehan, & Walrath-Greene, 2007). From this, researchers are able to understand multiple components that influence providers' attitudes towards EBP implementation, namely: appeal, requirements, openness and divergence. Firstly, appeal assesses how the information of EBP is introduced. For example, providers in general are more comfortable with information that has been introduced to them through their colleagues as opposed to research literature. This subscale has a Cronbach's alpha score of .80. Secondly, the extent to which a stakeholder complies with the requirements of an EBP refers to how someone reacts to the rules set out. This greatly impacts the way in which an EBP is executed. This subscale has a Cronbach's alpha score of .90 . Thirdly, openness encompasses a provider's willingness to try new interventions (Aarons et al., 2007). This subscale has a Cronbach's score of .78 (Aarons, 2004). Lastly, divergence refers to how a provider views an intervention as not useful, often when compared to current practices. This subscale has a

Cronbach's score of .59. The internal consistency reliability is reflected in the Cronbach's alpha which has an average of .77 (Aarons, 2004).

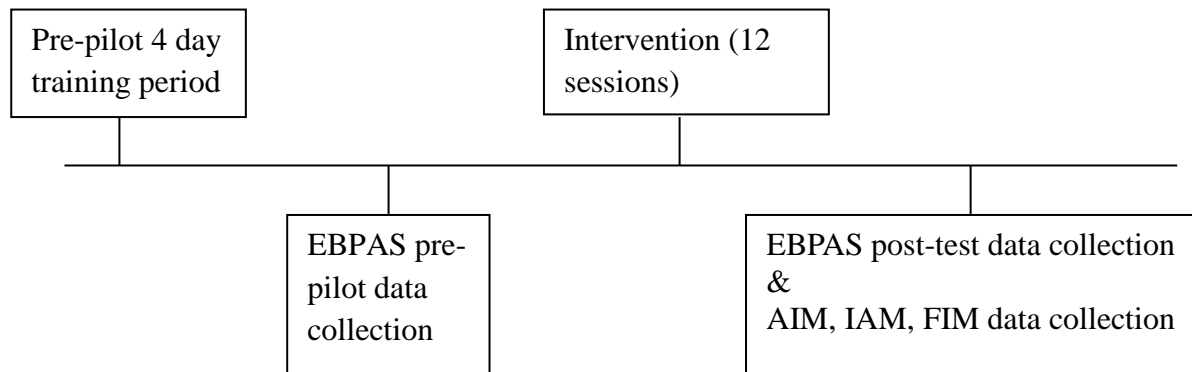
### **Procedure**

Firstly, a request to the Department of Education was submitted in order to be granted access to the two schools mentioned above. Participants were recruited through purposive sampling. ECD workers and their respective school supervisors attended a four day training workshop that introduced them to caregiver coaching skills and ESDM principles using C-ESDM training materials (Rogers et al., 2017). This took place at DCAP and consisted of didactic learning and introduction to the new coaching and ESDM skills. ECD workers were able to practice these new skills with a caregiver and child for two practice sessions.

The caregivers received twelve, one hour sessions of P-ESDM coaching from non-specialist Early Childhood Development workers. During these interactive sessions the caregivers are taught a new ESDM skill, using a 'help is in your hands' video. These videos provide instructions and show footage of other caregivers using the new skills. The caregivers are then coached in the new skill by an ECD worker. This portion of the session focuses on linking caregiver and child behaviours. The ECD workers were supervised by ESDM certified therapists during the intervention sessions.

Prior to the start of the caregiver coaching intervention, the EBPAS were administered to the ECD workers, school supervisors and ESD certified therapists. Following the twelve intervention sessions, the scale was re-administered. Caregivers did not complete this questionnaire (see Appendix B).

The AIM, IAM and FIM were administered once at the end of the coaching sessions because stakeholders needed experience with both components of the intervention, the caregiver coaching and C-ESDM 'help is in your hands', prior to completing these instruments (see Appendix C).



*Figure 1.* Data Collection Timeline

### **Ethical Considerations**

All study procedures were approved by the ethical review boards at Duke University and the University of Cape Town (Duke IRB Pro00064533 and UCT HREC 301/2015) (see Appendix D and E respectively). The study was approved by the Department of Education (see Appendix F). Prior to data collection, the research and study procedure was explained to each participant by a research assistant and the participants signed an informed consent form (see Appendix G).

### **Statistical analysis**

Statistical analyses were conducted using SPSS software. Statistical analysis is limited due to the fact that the pilot study has a limited number of participants. There are  $N=7$  participants for EBPAS data and  $N=9$  for AIM/IAM/FIM data. A paired-samples t-test was conducted to compare pre-test and post-test EBPAS scores. This method was used in similar ASD intervention studies using the same measure (Stahmer & Aarons, 2009). As the study has less than 30 participants, we cannot determine if the data is normally distributed. The AIM/IAM/FIM number of participants in each separate group participants was too small to run any statistical analyses that could determine between group differences (ECD workers  $n=2$ ; school supervisors  $n=2$ ; ESDM therapists  $n=3$ ; caregivers  $n=2$ ).

## Results

The results from the paired sample t-test show that there was no significant difference in the pre-test scores ( $M=4$ ,  $SD=.45$ ) and post-test scores ( $M=4.03$ ,  $SD=.43$ );  $t(6) = -.11$ ,  $p=0.92$ . This suggests that the exposure to the intervention does not significantly change stakeholders' attitude towards the intervention. With a very small observed power score of 0.51 the ability to detect an effect is improbable. There is a possibility that a larger sample size would show a significant difference in pre-test and post-test scores. Paired-sample t-tests were also conducted on each subscales' pre-test and post-test scores but none of them showed significant differences (see Table 1).

Table 1

*Pre-test and Post-test EBPAS Scores*

EBPAS Scale	Group	<i>M</i>	<i>SD</i>	<i>t</i>	<i>p</i>
Requirements	Pre-test	3.48	.84	-.80*	.457
	Post-test	3.76	.53		
Appeal	Pre-test	4.50	.52	.540**	.609
	Post-test	4.32	.49		
Openness	Pre-test	4.25	.76	-.528***	.617
	Post-test	4.46	.39		
Divergence	Pre-test	3.64	1.11	.496*****	.637
	Post-test	3.50	.89		
Total	Pre-test	4	.45	-.11*****	.917
	Post-test	4.03	.43		

Note. EBPAS = Evidence Based Practice Attitude Scale; *SD*= standard deviation

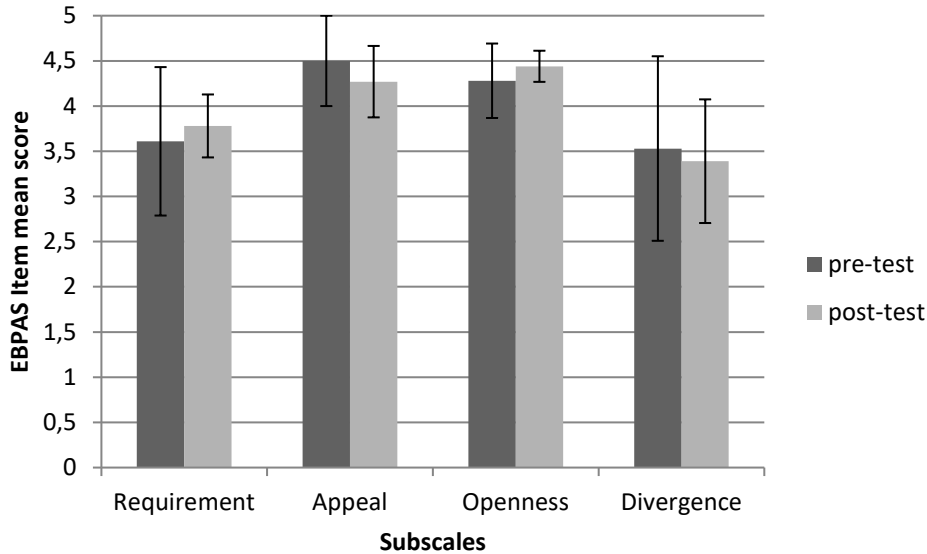


Figure 2. All groups subscale item means ( $N=7$ ).

Subscale of Appeal of all groups decreased from pre-test ( $M=4.5$ ;  $SD=0.5$ ) to post-test ( $M=4.27$ ;  $SD=0.4$ ), indicating that on average the stakeholders felt that EBPs made less sense to them and was less appealing after experiencing the intervention sessions. Subscale of Divergence also decreased from pre-test ( $M= 3.53$ ;  $SD= 1.02$ ) to post-test ( $M= 3.39$ ;  $SD= 0.68$ ) showing that stakeholders felt that P-ESDM was less clinically useful compared to clinical experience after taking part in the pilot study. However, the increase in Openness from pre-test ( $M= 4.28$ ;  $SD= 0.41$ ) to post-test ( $M= 4.44$ ;  $SD= 0.17$ ) suggests that following exposure to the intervention, stakeholders became more willing to trying new interventions and use EBPs. ESDM therapists had slightly higher post-test Openness subscale item mean scores ( $M= 4.58$ ;  $SD=0.88$ ) compared to ECD and SS.



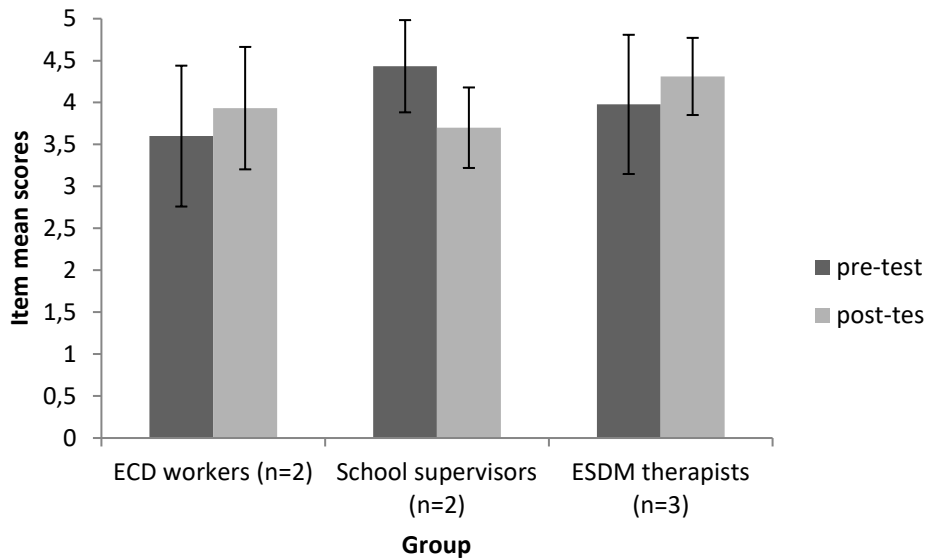


Figure 3. Groups total item means.

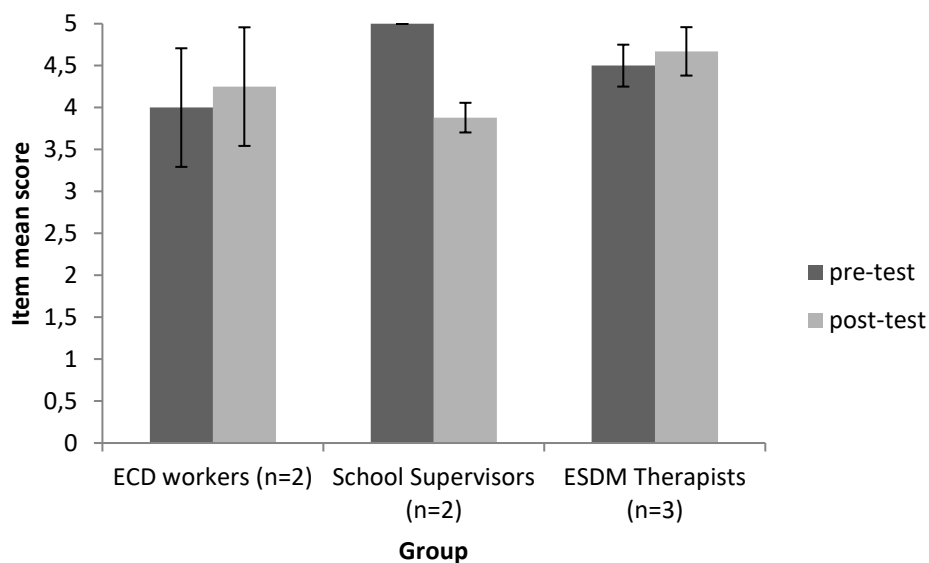


Figure 4. Appeal subscale item means.

From Figure 3 we can see that ECD workers pre-test scores ( $M=3.64$ ;  $SD=0.84$ ) increased to ( $M=3.95$ ;  $SD=0.73$ ) at post-test. ESDM therapists scores increased from pre-test scores ( $M=3.90$ ;  $SD=0.83$ ) to post-test scores ( $M=4.27$ ;  $SD=0.46$ ). The school supervisor group decreased from pre-test score ( $M=4.41$ ;  $SD=0.55$ ) to post-test score ( $M=3.69$ ;  $SD=0.48$ ). The greatest difference between school supervisor pre-test and post-test scores is from the Appeal subscale ( $M= 5$ ;  $SD=0$  to  $M= 3.88$ ;  $SD=0.18$ ). This indicates that after

exposure to the intervention, EBPs were no longer seen as intuitively appealing or that it makes less sense to them than before the intervention sessions. From Figure 3 we can see that all the participant groups' overall item means were above the neutral point of 3. This tells us that ultimately all participants had favourable attitudes towards EBPs.

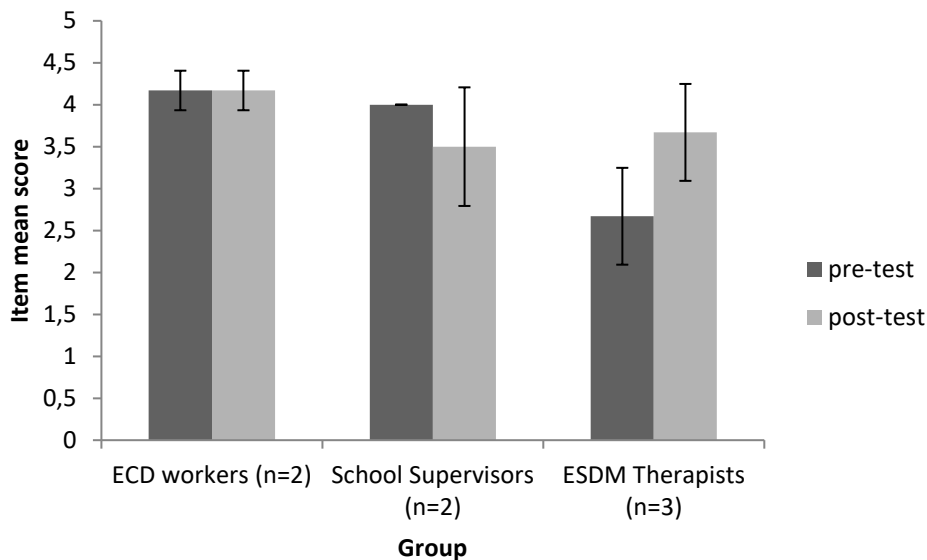


Figure 5. Requirement subscale item means.

ECD workers had the highest mean score for Requirements at pre-test and post-test ( $M= 4.17$ ;  $SD=0.24$ ) of all the stakeholder groups which indicates that this group is the most likely to adopt an EBP if required to do so by supervisor, employer or state. In comparison ESDM therapists had a much lower Requirement subscale score at pre-test ( $M= 2.67$ ;  $SD=0.58$ ) which increased to ( $M= 3.67$ ;  $SD=0.58$ ) at post-test but was still lower than ESD workers post-test scores.

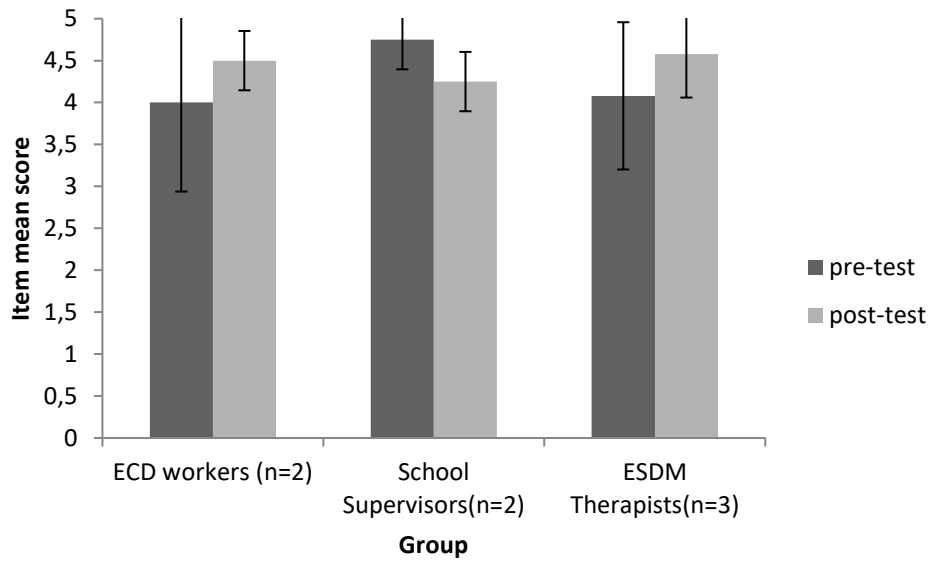


Figure 6. Openness subscale item means.

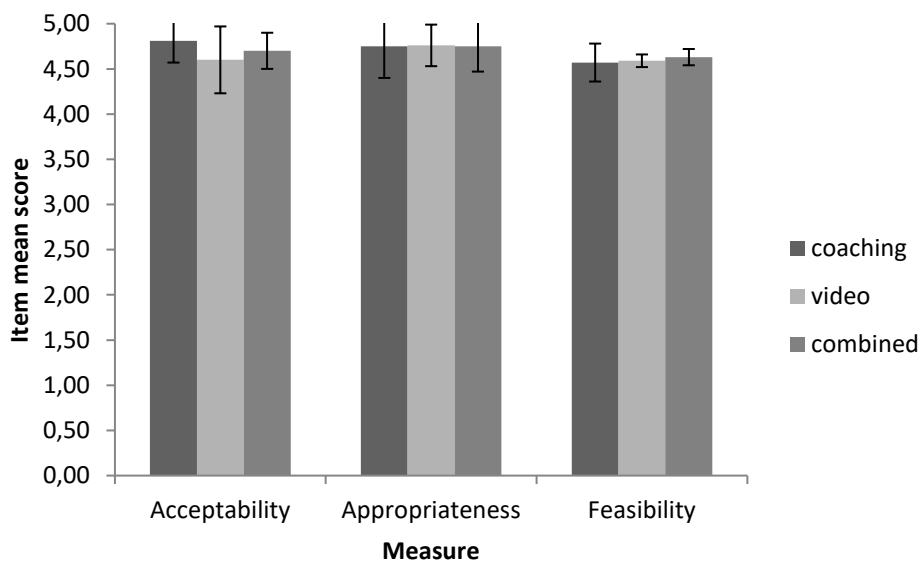


Figure 7. Groups total item means (N=9).

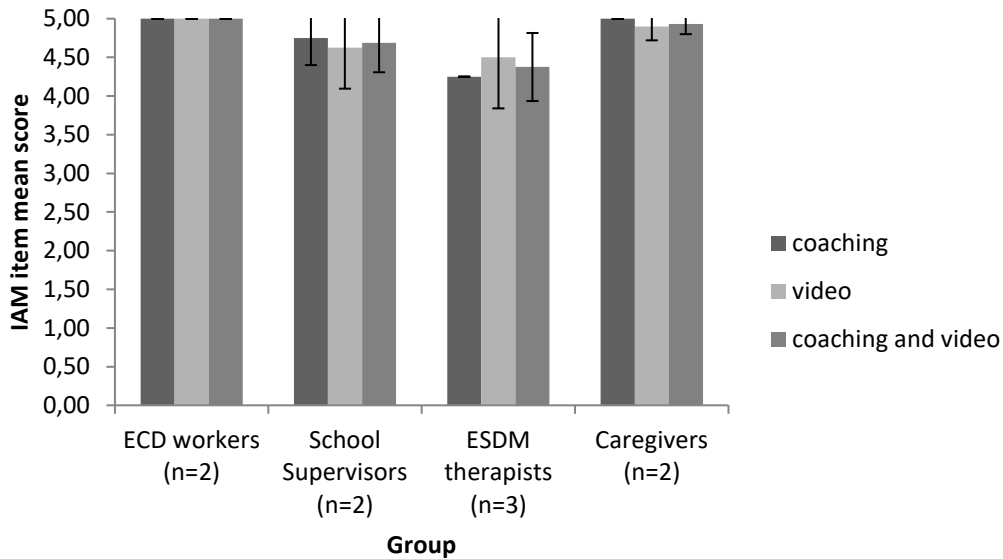


Figure 8. Appropriateness item means.

IAM had the highest overall mean item score combining coaching and video components ( $M=4.75$ ;  $SD=0.28$ ). When examining each group's appropriateness scores ECD workers had the highest score of  $M=5$  ( $SD=0$ ) for both the coaching and the video component of P-ESDM. This is the highest score possible indicating that this group found P-ESDM to be suitable for their use. School supervisors, ESDM therapists and caregivers all had a combined coaching and video component appropriate score above  $M=4$  which also indicates a high perceived appropriateness towards P-ESDM.

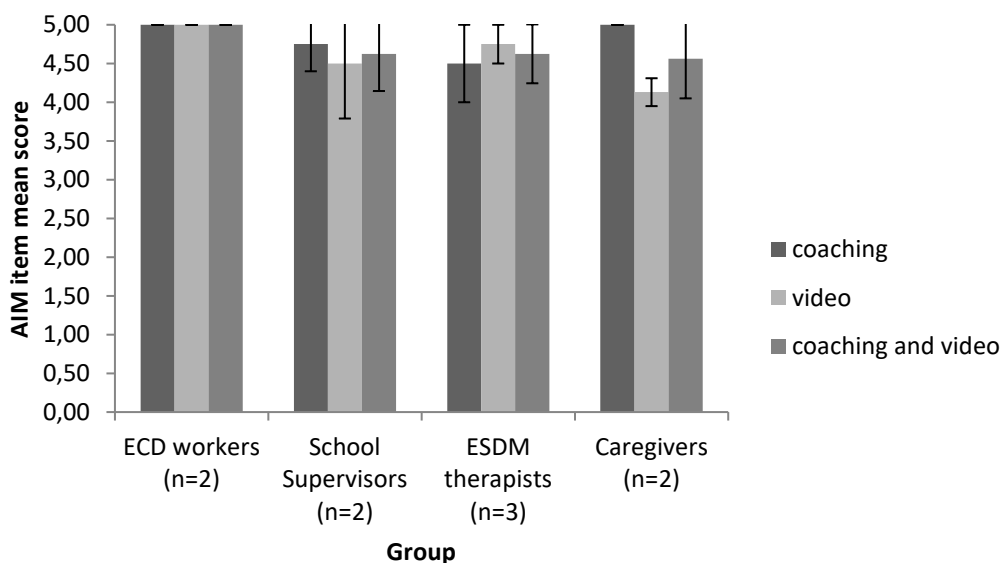


Figure 9. Acceptability item means.

The overall mean score for acceptability of all groups with combined coaching and video component scores is  $M= 4.70$  ( $SD=0.20$ ). This is a high score suggesting that on the whole the multi-stakeholders found the intervention to be extremely agreeable. The ECD workers group had the highest combined coaching and video component score with a mean score of  $M= 5$  ( $SD= 0$ ), the highest possible score. This indicates that out of all the stakeholder groups, ECD workers were the most confident that P-ESDM is satisfactory in their line of work. Caregivers had the lowest combined coaching and video appropriateness mean score of  $M= 4.56$  ( $SD=0.51$ ). However, this is still a relatively high score indicating that caregivers also view P-ESDM as being agreeable, just to a lesser extent than the other stakeholder groups. Coaching and video components both had high acceptability scores with coaching component having a 0.21 increase compared to the video component.

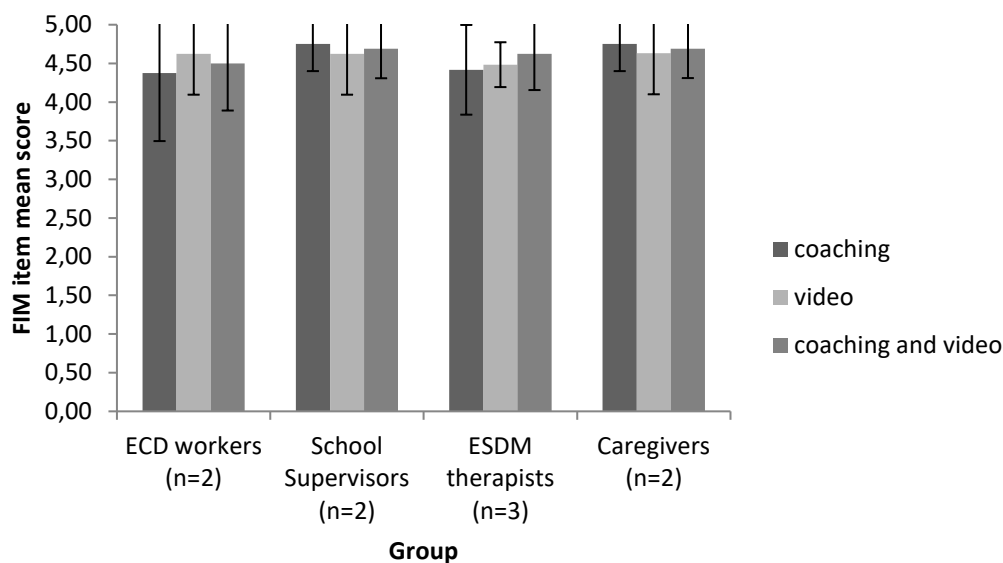


Figure 10. Feasibility item means.

The mean score for feasibility of all stakeholder groups combined coaching and video was the lowest of the three measures of FIM/AIM/IAM with a score of  $M= 4.63$  ( $SD= 0.09$ ). This is still a high score indicating that all stakeholders believe that P-ESDM can be

implemented successfully. Feasibility of the coaching ( $M=4.57$ ;  $SD=0.21$ ) and video component ( $M=4.59$ ;  $SD=0.07$ ) had almost identical item means indicating that both components were equally seen as feasible to the stakeholders. Interestingly, ECD workers had the lowest feasibility score for the coaching and video components combined from the groups ( $M=4.50$ ;  $SD=0.61$ ). As this pilot study aims for ECD workers to coach the caregivers in delivering P-ESDM, the ECD workers' belief that this intervention is able to be successful is of great importance.

### **Discussion**

EBPAS results indicate that all stakeholders had favourable attitudes towards EBPs. At pre-test school supervisors had the highest global positive attitudes towards EBPs but at post-test, ESDM therapists had the highest global positive attitudes. While ECD workers and ESDM therapists' attitudes became more positive towards EBPs from pre-test to post-test, school supervisors' attitudes became less positive. The school supervisors' noticeable decrease is worrying because they are the group that may have the influence over which intervention methods are adopted as heads of departments at their respective schools. Perhaps during the intervention period the reality of the extra effort the intervention required of school supervisors may have made them less open and enthusiastic towards it. This should be examined to ensure that the intervention does not become too overwhelming for stakeholders. This is especially important to consider in the future if the study is to be implemented on a greater scale as this would require ECD workers and school supervisors to work with a much greater number of caregiver child dyads, increasing their work load further.

Participants were more likely to adopt an EBP because it was required of them or because they were open to trying new interventions after exposure to the intervention period, and participants were less likely to adopt an EBP because it was appealing or because it was as useful and important as clinical experience after exposure to the intervention period. This

differs to other pre-test post-test results from studies using the same measure that found openness to new EBPs, the sense of appeal of a new EBP and its requirement to adopt it as increasing after exposure to an intervention (Matsuda & Kono, 2015). A possible reason for the differences in this study is that in South Africa, EBPs have not yet been widely accepted in the field of psychology. Empirical based research in psychology is not necessarily a focus point in psychology training programmes in the country which has resulted in professionals having a varied range of positions on the use of EBP (Kagee & Lund, 2012).

This study found that there were differences in attitudes towards EBPs across participant groups. ECD workers were shown to be the most likely to adopt an EBP because it was required of them, whilst ESDM certified therapists were the least likely to adopt an EBP because it was required of them. This is perhaps a reflection of the nature of their work, As there is no uniformity in the way EBPs are used in South Africa, clinicians that use EBPs do so because it is their personal choice (Kagee & Lund, 2012). This reflects a more individual-based motivation in making decisions about which practices to use. In comparison, ECD workers and teachers usually work according to a set curriculum. In this way, ECD workers may be more likely to adopt an EBP for requirement purposes as they are more used to having little choice in the methods and content they use in their professional lives compared to ESDM therapists.

Nakamura, Higa-Mcmillan, Okamura and Shimabukuro (2011) found that the higher the level of formal education, the more open participants were to adopting EBPs. Although ESDM therapists have the highest level of formal education in this study, they were only slightly more open to adopting EBPs in comparison to ECD workers and school supervisors. Again, this may be a result of varying exposure to EBPs in training. As EBPs are slowly making their way into practice in South Africa, despite their high level of qualification, South African ESDM therapists may not have been as exposed to EBPs as therapists from

international studies, making their openness towards EBPs in alignment with other groups who are not as qualified as they are (Kagee & Lund, 2012).

The AIM, IAM and FIM have been so recently published that no studies using these measures have yet been published. Therefore there are no other studies in which to compare the findings of this study to. Results showed that of the implementation outcomes, participants saw the intervention as being more acceptable than they saw it being appropriate or feasible. Many participants gave full scores for the AIM, IAM and FIM for both the coaching and video components and while they may have felt the intervention deserves such high scores, this is an example of a ceiling effect. This makes it difficult to determine between group differences. A greater range of possible responses for the items may result in greater response variability (Moret et al., 2007).

There seemed to be a ceiling effect with some of the participants only giving the highest possible scores for the AIM, IAM and FIM questions. This may be because of a social desirability effect, compounded by the fact that there is a small sample group which reduces anonymity so participants worried the researcher will be offended if they do not show positive regard for the intervention (King & Bruner, 2000). A caregiver participant who gave all 5/5 scores except in the one measure told the researcher afterwards that the reduced score for one measure was only because the quality of the videos were poor. The caregiver emphasised that it was not to do with the quality of the intervention. While the participant may indeed feel that the intervention was very acceptable, appropriate and feasible, there is also a chance that they were so grateful for the assistance the intervention provided their child that they did not want to appear ungrateful.

### **Limitations**

The major limitation of the study is the small sample size. This impacted greatly on the statistical analysis. However, the sample size was appropriate for a pilot project. An



additional limitation that should be considered is the fact that the ESDM therapists who were involved in the study have vested interests as they are also part of the research team. In this way, their questionnaire responses towards the interventions may have been influenced by their opinions as researchers, not just as their roles as ESDM therapists. While the stakeholders saw the intervention as being highly acceptable, appropriate and feasible, should the P-ESDM project be implemented on a larger scale, these implementation outcomes should be reassessed. The increased work load and effort of the stakeholders could affect their perception of the project, potentially making it seem less feasible.

### **Conclusion**

This study used implementation outcome measures to examine multi-stakeholders' perceptions of non-specialist delivered P-ESDM coaching. In doing so, it also addresses concerns that interventions in South Africa are not evidence-based. Overall, the results of this study demonstrate that stakeholders perceived the intervention to be highly appropriate, acceptable and feasible. The findings from this project show support for the successful adaption of a Western-developed intervention to suit a South African setting. These preliminary results indicate that the intervention can be piloted on a larger sample. This study contributes to the growing field of implementation science, research that is vital to determine the effectiveness and sustainability of EBPs in a community context.

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## Appendix A

Table 1

*Participant Demographic Data*

		ECD worker (n=2) (%)	School supervisor (n=2) (%)	ESDM therapist (n=3) (%)	Caregiver (n=2) (%)
Gender	Female	100	100	100	50
	Male	-	-	-	50
Ethnicity	African	50	-	33.33	-
	Coloured	50	-	-	100
	Indian	-	-	-	-
	White	-	100	66.66	-
Level of education	Tertiary	-	100	100	50
	Certificate	100	-	-	-
	Grade12/matric	-	-	-	50
First language	isiXhosa	50	-	-	-
	Afrikaans	50	100	33.33	-
	English	-	-	33.33	100
	isiZulu	-	-	33.33	-

## Appendix B

**Evidence-based Practice Attitude Scale****Date:** \_\_\_\_\_ **Subject ID:** \_\_\_\_\_

PLEASE READ QUESTIONS CAREFULLY

We want to **capture your impressions** about the therapy. Based on your impressions, **please indicate the extent to which you agree with each statement.**

- 1. I like to use new types of therapy/intervention to help my clients.**
  - A. Not at all
  - B. To a Slight Extent
  - C. To a Moderate Extent
  - D. To a Great Extent
  - E. To a Very Great Extent
  
- 2. I am willing to try new types of therapy/intervention even if I have to follow a treatment manual.**
  - A. Not at all
  - B. To a Slight Extent
  - C. To a Moderate Extent
  - D. To a Great Extent
  - E. To a Very Great Extent
  
- 3. I know better than academic researchers how to care for my client.**
  - A. Not at all
  - B. To a Slight Extent
  - C. To a Moderate Extent
  - D. To a Great Extent
  - E. To a Very Great Extent
  
- 4. I am willing to use new and different types of therapy/intervention developed by researchers.**
  - A. Not at all
  - B. To a Slight Extent
  - C. To a Moderate Extent
  - D. To a Great Extent
  - E. To a Very Great Extent
  
- 5. Research based treatments/interventions are not clinically useful.**

- A. Not at all
- B. To a Slight Extent
- C. To a Moderate Extent
- D. To a Great Extent
- E. To a Very Great Extent

**6. Clinical experience is more important than using manualized therapy/interventions.**

- A. Not at all
- B. To a Slight Extent
- C. To a Moderate Extent
- D. To a Great Extent
- E. To a Very Great Extent

**7. I would not use manualized therapy/interventions.**

- A. Not at all
- B. To a Slight Extent
- C. To a Moderate Extent
- D. To a Great Extent
- E. To a Very Great Extent

**8. I would try a new therapy/intervention even if it were very different from what I am used to doing.**

- A. Not at all
- B. To a Slight Extent
- C. To a Moderate Extent
- D. To a Great Extent
- E. To a Very Great Extent

**For questions 9-15: If you received training in a therapy that is new to you, how likely would you be to adopt it if:**

**9. It was naturally appealing?**

- A. Not at all
- B. To a Slight Extent
- C. To a Moderate Extent
- D. To a Great Extent
- E. To a Very Great Extent

**10. It "made sense" to you?**

- A. Not at all
- B. To a Slight Extent
- C. To a Moderate Extent
- D. To a Great Extent
- E. To a Very Great Extent

**11. It was required by your supervisor?**

- A. Not at all
- B. To a Slight Extent
- C. To a Moderate Extent
- D. To a Great Extent
- E. To a Very Great Extent

**12. It was required by your school?**

- A. Not at all
- B. To a Slight Extent
- C. To a Moderate Extent
- D. To a Great Extent
- E. To a Very Great Extent

**13. It was required by your Province?**

- A. Not at all
- B. To a Slight Extent
- C. To a Moderate Extent
- D. To a Great Extent
- E. To a Very Great Extent

**14. It was being used by colleagues who were happy with it?**

- A. Not at all
- B. To a Slight Extent
- C. To a Moderate Extent
- D. To a Great Extent
- E. To a Very Great Extent

**15. You feel you have enough training to do it correctly?**

- A. Not at all
- B. To a Slight Extent
- C. To a Moderate Extent
- D. To a Great Extent
- E. To a Very Great Extent

### Appendix C

#### Acceptability of Intervention Measure (AIM)/ Intervention Appropriateness Measure (IAM)/ Feasibility of Intervention Measure (FIM)

**Date:** \_\_\_\_\_ **Subject ID:** \_\_\_\_\_

#### Acceptability (AIM): Coaching

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The coaching sessions met my approval.	①	②	③	④	⑤
2. The coaching sessions are appealing to me.	①	②	③	④	⑤
3. I like the coaching sessions.	①	②	③	④	⑤
4. I welcome the coaching sessions.	①	②	③	④	⑤

#### Acceptability (AIM): Videos

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The videos met my approval.	①	②	③	④	⑤
2. The videos are appealing to me.	①	②	③	④	⑤
3. I like the videos.	①	②	③	④	⑤
4. I welcome the videos.	①	②	③	④	⑤

#### Appropriateness (IAM): Coaching

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree



1. The coaching sessions seem fitting.	①	②	③	④	⑤
2. The coaching sessions seem suitable.	①	②	③	④	⑤
3. The coaching sessions seem applicable.	①	②	③	④	⑤
4. The coaching sessions seem like a good match.	①	②	③	④	⑤

### Appropriateness (IAM): Videos

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The videos seem fitting.	①	②	③	④	⑤
2. The videos seem suitable.	①	②	③	④	⑤
3. The videos seem applicable.	①	②	③	④	⑤
4. The videos seem like a good match.	①	②	③	④	⑤

### Feasibility (FIM): Coaching

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The coaching sessions seem workable.	①	②	③	④	⑤
2. The coaching sessions seem possible.	①	②	③	④	⑤
3. The coaching sessions seem doable.	①	②	③	④	⑤
4. The coaching sessions seem easy to use.	①	②	③	④	⑤

**Feasibility (FIM): Videos**

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The videos seem workable.	①	②	③	④	⑤
2. The videos seem possible.	①	②	③	④	⑤
3. The videos seem doable.	①	②	③	④	⑤
4. The videos seem easy to use.	①	②	③	④	⑤

## Appendix D

## Duke University Ethical Approval

**IRB NOTIFICATION OF CONTINUING REVIEW APPROVAL**

**Protocol ID:** Pro00064533

**Reference ID:** 268907

**Principal Investigator:** Lauren Franz

**Protocol Title:** Pilot Study to Improve Access to Early Intervention for Autism in Africa

**Sponsor/Funding Source(s):** National Institute of Health(824), National Institutes of Mental Health(824)

**Federal Funding Agency ID:**

**Date of Declared Concordance with federally funded grant, if applicable:** N/A

The Duke University Health System Institutional Review Board for Clinical Investigations has conducted the following activity on the study cited above:

**Activity:** Continuing Review

**Review Type:** Expedited

**Review Date:** 8/2/2018

**Issue Date:** 8/6/2018

**Anniversary Date:**

**Expiration Date:** 08/11/2019

DUHS IRB approval encompasses the following specific components of the study:

<b>Protocol, version/date:</b>	-3/19/2018
<b>Summary, version/date:</b>	-
<b>Consent form reference date:</b>	-
<b>Investigator Brochure, version/date:</b>	-
<b>Pediatric Risk Category:</b>	-
<b>Other:</b>	- Consent Templates

The DUHS IRB has determined the specific components above to be in compliance with all applicable Health Insurance Portability and Accountability Act ("HIPAA") regulations.

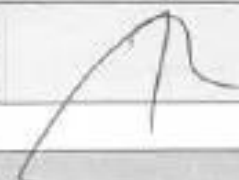
This study expires at 12 AM on the Expiration Date cited above. At that time, all study activity must cease. If you wish to continue specific study activities directly related to subject safety, you must immediately email Jody Power at [jody.power@duke.edu](mailto:jody.power@duke.edu) or call the IRB Office at 919-668-5111 and follow the instructions to reach the IRB Chair on call. Continuing review submissions (renewals) must be received by the DUHS IRB office 60 to 45 days prior to the Expiration Date.

No change to the protocol, consent form or other approved document may be implemented without first obtaining IRB approval for the change. Any proposed change must be submitted as an amendment. If necessary in a life-threatening situation, where time does not permit your prior consultation with the IRB, you may act contrary to the protocol if the action is in the best interest of the subject. You must notify the IRB of your action within five (5) working days of the event.

The Duke University Health System Institutional Review Board for Clinical Investigations (DUHS IRB), is duly constituted, fulfilling all requirements for diversity, and has written procedures for initial and continuing review of human research protocols. The DUHS IRB complies with all U.S. regulatory requirements related to the protection of human research participants. Specifically, the DUHS IRB complies with 45CFR46, 21CFR50, 21CFR56, 21CFR312, 21CFR812, and 45CFR164.508-514. In addition, the DUHS IRB complies with the Guidelines of the International Conference on Harmonization to the extent required by the U. S. Food and Drug Administration.

Appendix E  
UCT Ethics Approval

 <b>UNIVERSITY OF CAPE TOWN</b> <small>UNIVERSITEIT VAN KAPSTAD</small>	<b>HUMAN RESEARCH ETHICS COMMITTEE</b> 14 JUN 2018 HEALTH SCIENCES FACULTY	<b>FACULTY OF HEALTH SCIENCES</b> Human Research Ethics Committee	
<b>FHS016: Annual Progress Report / Renewal</b>			

<b>HREC office use only (FWA00001637; IRB00001938)</b>			
This serves as notification of annual approval including any documentation described below.			
<input checked="" type="checkbox"/> Approved	Annual progress report	Approved until/next renewal date	30/06/2019
<input type="checkbox"/> Not approved	See attached comments		
Signature Chairperson of the HREC			Date Signed
			15/6/18

Comments to PI from the HREC

**Principal Investigator to complete the following:**

**1. Protocol Information**

Date (when submitting this form)	14 June 2018		
HREC REF Number	301/2015	Current Ethics Approval was granted until	30 <sup>th</sup> July 2018
Protocol title	Pilot Study to Improve Access to Early Intervention for Autism in Africa		
Protocol number (if applicable)	301/2015		
Are there any sub-studies linked to this study?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
If yes, could you please provide the HREC Ref's for all sub-studies? Note: A separate FHS016 must be submitted for each sub-study.			
Principal Investigator	Prof Petrus J de Vries		
Department / Office Internal Mail Address	Division of Child & Adolescent Psychiatry 46 Sawkins Road Rondebosch		

1.1 Does this protocol receive US Federal funding?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
1.3 Has sponsorship of this study changed? If yes, please attach a revised summary of the budget.	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No



## 2. List of documentation for approval

None

## 3. Protocol status (tick ✓)

<input checked="" type="checkbox"/>	Open to enrolment
<input type="checkbox"/>	Closed to enrolment (tick ✓)
<input type="checkbox"/>	Research-related activities are ongoing
<input type="checkbox"/>	Research-related activities are complete, long-term follow-up only
<input type="checkbox"/>	Research-related activities are complete, data analysis only
<input type="checkbox"/>	Main study is complete but sub-study research-related activities are ongoing
<input type="checkbox"/>	Study is closed → Please submit a Study Closure Form (FHS010)

## 4. Enrolment

Number of participants enrolled to date	37
Number of participants enrolled, since last HREC Progress report (continuing review)	11
Additional number of participants still required	50

## 5. Refusals

Total number of refusals (participants invited to join the study, but refused to take part)	0
---	---

## 6. Cumulative summary of participants

Total number of participants who provided consent	37
Number of participants determined to be ineligible (i.e. after screening)	0
Number of participants currently active on the study	37
Number of participants completed study (without events leading to withdrawal)	37
Number of participants withdrawn at participants' request (i.e. changed their mind)	0
Number of participants withdrawn by PI due to toxicity or adverse events	0
Number of participants withdrawn by PI for other reasons (e.g. pregnancy, poor compliance)	0
Number of participants lost to follow-up. Please comment below on reasons for loss of follow-up.	0
Number of participants no longer taking part for reasons not listed above. Please provide reasons below:	0



## 7. Progress of study

Please provide a brief summary of the research to date including the overall progress and the progress since the last annual report as well as any relevant comments/issues you would like to report to the HREC:

Project-specific goals in year 3 focused on (1) Early Start Denver Model (ESDM) certification of three local clinicians who function as supervisors of Early Childhood Development non-specialist workers on her project, (2) gathering and analyzing qualitative data from multiple stakeholders that has identified Early Childhood Development workers employed by the Education Department as potentially sustainable providers of early ASD intervention in South Africa and (3) training 2 Early Childhood Development workers and starting a pre-pilot where the non-specialists deliver twelve, 1 hour per week caregiver coaching sessions to caregiver-child dyads. Importantly, the pre-pilot will provide information on the feasibility of the training and supervision structure as well as the study measures. In addition, the pre-pilot will inform modifications to our approach for the pilot study that will begin in year 4 of the K01.

Academic products over the past year relevant to the K01 include publication of the following manuscript: *Guler J, de Vries PJ, Seris N, Shabalala N, Franz L. The importance of context in early autism intervention: A qualitative South African study. Autism: International Journal of Research and Practice. Published online: September 15, 2017. PMID: PMC5832543.* In this manuscript contextual factors relevant to the adaptation of a caregiver coaching early ASD intervention in a low-resource South African setting are presented. The following manuscript is currently being revised for publication: *Franz L, Adewumi K, Chambers N, Viljoen M, Baumgartner J, de Vries PJ. Providing early detection and intervention for autism spectrum disorder in South Africa: Stakeholder perspectives.* This manuscript describes key stakeholder perspectives in Health, Education, Social Development and the non-profit sector in the Western Cape Province of South Africa on early detection and early intervention for ASD. The following manuscript is currently in preparation: *Caregiver descriptions of joint activity routines for early autism spectrum disorder intervention in South Africa. Ramseur K, de Vries PJ, Guler J, Shabalala N, Seris N, Franz L.* This manuscript provides qualitative descriptions of caregiver-child joint activity routines in order to understand whether caregiver coaching early intervention could fit in a low resource South African setting.

## 8. Protocol violations and exceptions (tick ✓ all that apply)

<input checked="" type="checkbox"/>	No prior violations or exceptions have occurred since the original approval
<input type="checkbox"/>	Prior violations or exceptions have been reported since the last review and have already been acknowledged or approved
<input type="checkbox"/>	Unreported minor violations that have occurred since the last review, as well as significant deviations not yet reported, are attached for review

## 9. Amendments (tick ✓ all that apply)

<input type="checkbox"/>	No prior amendments have been made since the original approval
<input type="checkbox"/>	Prior amendments have been reported since the last review and have already been approved
<input checked="" type="checkbox"/>	New protocol changes/ amendments are requested as part of this continuing review (See note below)

Note: If new protocol changes are being requested in this review, please complete an amendment form (FHS006).

Specific changes in the amended protocol and consent/assent forms must be **bolded**, *italised* or tracked and all changes must include a rationale.



## 10. Adverse events

10.1 Please provide below or attach a narrative summary of serious adverse events and/ or unanticipated problems since the last progress report. Please indicate changes made to the protocol and informed consent document(s) as a result (if not already reported to the HREC). Please comment on whether causality to any study procedure or intervention could be established.

None

10.2 Have participants received appropriate treatment/ follow-up/ referral when indicated (e.g. in the case of abnormal or incidental clinical findings, distress or anxiety)?

Yes  No  Not applicable

If yes, please describe:

--

## 11. Summary of Monitoring and Audit Activities (tick ✓)

11.1 Was this study monitored or audited by an external agency (e.g. MCC, FDA)?

Yes  No  Not applicable

11.2 Did a Data and Safety Monitoring Board publish a report?

Yes  No  Not applicable

11.3 If yes, please identify the agency and attach a summary of the findings.

Agency Name	Report attached	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable
	DSMB report attached	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not applicable

11.4 Has there been any agency, institutional or other inquiry into non-compliance in this study, or any finding of non-compliance concerning a member of the research team?

Yes  No

If yes, please explain:

--


**12. Level of risk (tick ✓)**

12.1 In light of your experience of this research, please indicate whether the level of risk to participants has:

- |                                     |                 |
|-------------------------------------|-----------------|
| <input type="checkbox"/>            | Increased       |
| <input type="checkbox"/>            | Decreased       |
| <input checked="" type="checkbox"/> | Shown no change |

If there has been a change, please explain:

12.2 Please provide a narrative summary of recent relevant literature that may have a bearing on the level of risk.

Increased risk from participation in early behavioural interventions for autism spectrum disorder have not been documented in the literature.

**13. Statement of conflict of interest**

Has there been any change in the conflict of interest status of this protocol since the original approval? (tick ✓)

- |                              |  |
|------------------------------|--|
| <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
|------------------------------|--|

If yes, please explain and if necessary attach a revised conflict of interest statement (Section #7 in the New Protocol Application Form FHS013):

**14. Signature**

My signature certifies that the above is complete and correct.

Signature of PI		Date	14 June 2018
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## Appendix F

## Department of Education Approval

[Audrey.wyngaard@westerncape.gov.za](mailto:Audrey.wyngaard@westerncape.gov.za)

tel: +27 021 467 9272

Fax: 0865902282

Private Bag x9114, Cape Town, 8000

wced.wcape.gov.za

**REFERENCE:** 20180215-9358**ENQUIRIES:** Dr A T Wyngaard

Ms Marisa Viljoen  
Building B, Division of Child and Adolescent Psychiatry  
46 Sawkins Road  
Rondebosch  
7700

**Dear Ms Marisa Viljoen****RESEARCH PROPOSAL: PILOT STUDY TO IMPROVE ACCESS TO EARLY INTERVENTION FOR AUTISM IN AFRICA**

Your application to conduct the above-mentioned research in schools in the Western Cape has been approved subject to the following conditions:

1. Principals, educators and learners are under no obligation to assist you in your investigation.
2. Principals, educators, learners and schools should not be identifiable in any way from the results of the investigation.
3. You make all the arrangements concerning your investigation.
4. Educators' programmes are not to be interrupted.
5. The Study is to be conducted from **16 February 2018 till 30 January 2021**
6. No research can be conducted during the fourth term as schools are preparing and finalizing syllabi for examinations (October to December).
7. Should you wish to extend the period of your survey, please contact Dr A.T Wyngaard at the contact numbers above quoting the reference number?
8. A photocopy of this letter is submitted to the principal where the intended research is to be conducted.
9. Your research will be limited to the list of schools as forwarded to the Western Cape Education Department.
10. A brief summary of the content, findings and recommendations is provided to the Director: Research Services.
11. The Department receives a copy of the completed report/dissertation/thesis addressed to:

**The Director: Research Services  
Western Cape Education Department  
Private Bag X9114  
CAPE TOWN  
8000**

We wish you success in your research.

Kind regards.

Signed: Dr Audrey T Wyngaard

**Directorate: Research**

**DATE: 19 February 2018**

## Appendix G

## Consent Form

**FORM 4 (INDIVIDUAL INTERVIEWS AND QUESTIONNAIRE)  
CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

**Title of the Research Project: “Pilot Study to Improve Access to Early Intervention for Autism in Africa”**

**PRINCIPAL INVESTIGATOR:** Prof. Petrus de Vries

**ADDRESS:** Division of Child and Adolescent Psychiatry, 46 Sawkins Road, Rondebosch, Cape Town, 7700

**Tel:** 021-685 4103

You are being invited to take part in a research project. Please take some time to read the information below, which will explain the details of this project. Please ask the study staff any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied and that you clearly understand what this research is about. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the **Human Research Ethics Committee of the Faculty of Health Sciences of the University of Cape Town**. The study will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

**What is this research study all about?**

- We want to see how a treatment for autism, that can be taught to parents, works in South Africa. The name of this treatment is the “Parent Early-Start Denver Model”. This treatment has been shown to work with parents and their children with autism in the United States. From working with you we will learn how this treatment can be successfully delivered in South Africa.
- You are being asked to take part in an individual interview. The interview will last 1 hour.
- You are being asked to complete a 15-item questionnaire at two different times.
- We will be asking you questions that will help us understand what you think about the treatment for autism and what we might need to change to make it work better in South Africa.
- To be part of this study you must be over the age of 18, and have the legal right to sign this consent form.

- We will read through this form with you. Please ask if there any words that you do not understand. If you agree to be part of this study, you will sign this form.

**Why have you been invited to participate?**

- We are working with people who can help us understand if a treatment for young children with autism can be delivered in South Africa.
- You have received training in this autism treatment so your participation will help us learn more about how practical it would be to deliver this treatment in South Africa.

**What will your responsibilities be?**

- Your responsibility will be to try and answer the questions you are asked about your impressions of the autism intervention to the best of your ability.

**Will you benefit from taking part in this research?**

- You will not benefit directly from this research. You will help us learn more about whether this autism treatment can work for South African families.

**Are there risks involved in your taking part in this research?**

- No risk greater than those experienced in ordinary conversation are anticipated.
- We will make every effort to keep your information confidential and protected. No information will be shared with anyone outside of the study team. All documents and recordings will be stored in a locked filing cabinet or on a password protected computer. Your study information will be identified only by a number, not your name. Any documents containing your name and personal information will be kept separate from other study records, and will be stored in a secure way. If we write about this work, your identity will remain anonymous.
- These are the main risks. Please tell us if you have any worries about this information.

**Who else will be part of the study team?**

- The study team includes the principal investigator listed above, clinicians who work with children and families affected by autism, and research assistants.

**If you do not agree to take part, what alternatives do you have?**

- You are free not to take part or to withdraw at any time during the study.

**Will you be paid to take part in this study?**

- No, you will not be paid to take part in the study but your time and transportation will be covered for your study visit. The study staff will give you R100 for your visit. There will be no costs involved for you, if you do take part.

**May you choose to not participate or to withdraw from this study?**

- You may choose not to be in the study. If you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, we will not ask for any more information from you. All data that have already been collected for the study will be kept.

**In case of an emergency or if you feel you need to contact the Principal Investigator about questions or problems, you can do so by phoning: Dr. Petrus de Vries at tel no 021-685 4103 (petrus.devries@uct.ac.za)**

- You can also contact the Human Research Ethics Committee of the Health Sciences Faculty of the University of Cape Town 021-4066338 (lamees.emjedi@uct.ac.za ) if you have any concerns or complaints that have not been adequately addressed.

## Declaration by participant

By signing below, I ..... agree to take part in a research study entitled: **“Pilot Study to Improve Access to Early Intervention for Autism in Africa”**

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.

Signed at (*place*) ..... on (*date*) .....  
20\_\_.

.....  
**Signature of participant**

## Declaration by investigator/study coordinator

I (*name*) ..... declare that:

- I explained the information in this document to .....
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I will maintain confidentiality at all times.

Signed at (*place*) ..... on (*date*) .....  
20\_\_.

.....  
**Signature of investigator**