



טופס בקשה לאישור של ועדת אתיקה למחקרים בבני אדם

כל העוסק במחקר בו מעורבים בני אדם חייב בתעודה שעבר/ה הכשרה אתית

הטופס כתוב בלשון זכר אולם הוא מתייחס לחוקרות ולחוקרים כאחד

תאריך: 18/06/2020

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1. נושא המחקר:

This study proposes to assess the efficacy of an evidence-based, parent-mediated intervention (Social ABCs) for children recently diagnosed with autism spectrum disorder (ASD) and their parents.

2. סיכום קצר של המחקר ומטרותיו:

The Social ABCs is an evidence-based, parent-mediated intervention for toddlers (12-36 months) with autism or related social-communication challenges. The study has two phases. The first involves recruiting providing the intervention directly to the children. The second involves coaching parents in these techniques, so that they can work with their children more intensively long-term. All sessions will be videotaped for the purposes of research. The therapists (Dr. Koller and two graduate students in the School of Education: Tamar Matz and Tamar David) are being trained in the intervention by Canadian collaborators. Therefore, these trainers will virtually (Zoom) join a portion of the meetings with families in order to supervise and train the interventionists.

The Social ABCs focuses on two primary skills: language development and shared social affect. The research team will use the parent manual to help guide the children, and then the parents, to begin implementing specific skills/techniques in their daily routines. The goal of the research project is to assess the efficacy of the Social ABCs. Upon completion of the campus-based stage of training, we will evaluate the feasibility and efficacy of delivering the Social ABCs intervention in Israel using formal outcome measures, such as parent implementation fidelity, child responsiveness, etc. We will also



examine a number of novel family and parent-specific characteristics as outcome measures and predictors. The families will meet with a member of the research team, either individually or in groups, over the course of six weeks. In some cases the meetings will be didactic, wherein the researcher will be teaching the parent the background needed to implement the intervention, and in other cases the meetings will be interactive, wherein the researcher will be interacting with the child or will be guiding the parent in their interaction with the child.

3. מקור מימון המחקר פנים אוניברסיטאי, חיצוני, מימון עצמי:

This research is funded by the Canadian Friends of the Hebrew University.

4. תיאור משתתפי המחקר והאוכלוסייה ממנה ייבחרו כולל מספר המשתתפים:

Study population:

50 children aged 12-36 months who have recently been diagnosed with ASD, and their primary caregiver(s). The children will be recruited from a variety of avenues, including those who go through the diagnostic process at Clalit and will be referred to our study.

5. דרך בחירת המשתתפים, כולל קריטריוני הכללה:

The children must be between 12-36 months with an officially recognized diagnosis of ASD.

6. נוהל איסוף הנתונים (במידה של שימוש בשאלונים יש לצרפם לבקשה) ומשך המחקר המתוכנן:

The parents will complete questionnaires. In addition, certain standardized measures will also be given to the children directly, including a social-behavioral assessment (Autism Diagnostic Observation Scale-2), a cognitive assessment (Mullen), a language assessment (Preschool Language Scale-4), an adaptive behavior assessment (Adaptive Behavior Assessment System-2) and an autism severity scale assessment (SRS-2/ASRS). Each group/individual will meet 15 times, for 1-1.5 hours each meeting, over the course of the 6 weeks. The meetings will gradually decrease in frequency, starting with three



times per week for the first three weeks of the intervention. In the initial phase, clinicians will work directly with children for the purposes of training. These sessions will be recorded and supervised both through video and live. The project overall is planned to run for two years.

7. תיאור הסיכונים הצפויים לנבדק (כולל חוסר נוחות אפשרית בתחום הגופני, הפסיכולוגי, החברתי, הכלכלי או אחר), שעלולים להיגרם כתוצאה מהמעורבות במחקר. התייחס בבקשה הן להסתברות הסיכון והן לחומרתו:

No risk is expected. Parents might experience mild discomfort while discussing their child's developmental delays in a group format, but it is expected that they will also experience a degree of comfort and support from the other group members

8. האמצעים שיינקטו למזער את הסיכונים או אי הנוחות האפשריים:

No parent will be forced to talk in groups and every participant will know that they are able to withdraw from the study at any point with no repercussions.

10. תיאור התועלת האפשרית מעריכת המחקר עבור המשתתפים עצמם, אוכלוסיית המשתתפים והחברה:

As previously mentioned, the participants will be receiving an intervention, which will help them address some of their child's social-communication skills. This kind of intervention would otherwise be very expensive for the participants. Should the intervention prove effective, it could be used for many young children who have just been diagnosed. These families are often not immediately placed in a special education kindergarten or other intervention program, and as such this could serve in the interim to help them move forward with help for their children. More generally, knowledge about how the Social ABCs can impact the social and linguistic development of children with autism will contribute to the growing body of research about how to best address the needs of this population.

10. מתן הסבר כיצד עולה התועלת האפשרית מהמחקר על הסיכונים האפשריים ממנו, וכיצד ניתן להצדיק סיכונים אלה:

As mentioned above, the only potential risk is the mild discomfort the parents may feel about sharing their child's difficulties in a group setting. However, the potential outcomes the intervention may provide for these families, and specifically these children, far outweigh the risks.

11. אילו אמצעים ינקטו להבטחת חשאיות המשתתפים במחקר ולהגנת המידע והנתונים שייאספו על המשתתפים:

All the information collected on the participants will be anonymized before the data is entered into an online system. Each participant will receive a random number to identify them in the system. As the intervention meetings will be filmed, the videos will be uploaded into a secure system and will not be shared outside of the research study team unless the participant signs an informed consent. All these details will be included in the informed consent form the participants will sign before joining the study.

12. כיצד תישמר הגישה אל הנתונים:

Only the researchers in the study will have access to the data and the videos. The data will be password-protected.

13. כיצד תישמר זהות המשתתפים:

The names of the participants will be kept separately from the rest of the study materials.

14. האם יהיה תשלום לנבדקים ואם כן, באיזה סכום, כיצד הוא יינתן ומתי:

No payment will be offered.

15. ההסכמה להשתתף במחקר - מי אחראי על קבלת ההסכמה מדעת מהנבדק:

The families who agree to participate in the study will be given an informed consent form in the baseline meeting, which they will be required to sign before continuing with the study. The consent form will be kept in the study files and will be collected by the researcher leading the meeting.

16. באיזה אופן תתקבל ההסכמה, איפה ומתי:

The informed consent form will be given to the participant at the beginning of the baseline meeting. They will read it, the researcher will answer any questions regarding the form, and then the participant will sign before continuing with the process. Should an in-person meeting not be possible, the informed consent will be sent to the participants via email, the



researchers will be available to answer questions regarding the content, and the participants will have to electronically sign and return the form before continuing with the intervention process.

יש לצרף טופס ההסכמה שייעשה בו שימוש במחקר – ראו נספח בנושא, בהמשך טופס זה

חתימת החוקר:

החלטת הועדה: _____

