Single-Session Psychotherapy for Parents of Young Kids through Patient Engagement Techniques

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Project Research Question(s)

Summary of Main Goals

Recent research in our lab has shown that parents of children with neurodevelopmental disorders (NDDs) experience elevated parenting stress, especially in light of the COVID-19 pandemic. The SPYKids Program seeks to provide a first step to encouraging hope for parents of children with NDDs on waiting lists and improve their ability to cope with family stressors

through a single session consultation model. SPYKids has been designed for families on waitlists at local organizations, such as Specialized Services for Children and Youth (SSCY), St.Amant, MATC, and KIDTHINK. The purpose of this single-session intervention (SSI) is not to completely resolve challenges, but to provide parents with some help, encouragement, and motivation in the interim while waiting for more comprehensive services. A parent advisory panel and service providers have informed program development aligned with parent-driven priorities that enhance quality of care and long-term child outcomes (PSREB Approval P2020:064 at the University of Manitoba; Ref # 2013 at SSCY). Team expertise has informed the creation of a program that complements existing services and has sustainable impacts on child well-being. Now we seek to conduct a pilot randomized control trial on the SPYKids program. Our main goals are to determine the feasibility and acceptability of the SPYKids Program compared to services as usual (SAU; provincial waitlists for assessments or services, including SSCY service waitlists). We are also interested in changes in parenting stress, mental health, and parent and child well-being between the SPYKids and SAU groups before and after the SSI.

Project Description

Background and Rationale

Neurodevelopmental disorders, including attention deficit hyperactivity, autism, and fetal alcohol spectrum disorders, are experienced by 7-14% of Canadian children and represent the leading cause of disability in childhood.[1] Symptoms of NDDs, such as difficulties with communication and impulsivity, are linked to impaired quality of life, with commonly co-occurring behaviour and emotional (i.e., mental health) problems exacerbating the burden of illness.[2] In fact, emergent mental health problems are more closely linked to family distress than

diagnosis-specific symptoms, with over 85% of families reporting clinically elevated parenting stress and low child quality of life.[3,4] Up to 70% of children with NDDs will go on to develop additional mental illness in childhood, further highlighting the importance of early intervention.[5] Supportive parent-child relationships are critical for promoting resilient long-term development in children with NDDs.[6,7] Familial influences are particularly pronounced in the first 5 years, when children develop foundational emotional and behavioural regulation skills.[8] During this time, children benefit greatly from supportive parenting to understand their emotional experiences, learn to cope with distress, and manage impulsivity in prosocial ways.[9,10] Despite the importance of early intervention for promoting positive mental health, less than 25% of families of children with NDDs receive services.[11,12] This is due, in part, to lengthy waitlists for initial assessments (up to 1.5 years in Manitoba) and high therapeutic dropout rates, with families attending an average of 3.9 of 16 recommended sessions.[11,12] There is **immediate and critical need** for novel approaches that provide accessible front-line, timely support to families.

Parent-directed single-session interventions (SSIs) are designed to increase parental ability to understand and address emergent mental health problems. Defined as "specific, structured programs that intentionally involve just one visit or encounter with a provider," SSIs can teach parents how to support children's emotional development and impulse control to reduce mental health problems, while reducing high-conflict parenting that can worsen mental health over time. SSIs offer a highly scalable approach, with demonstrated efficacy (medium effects) across a variety of psychiatric concerns.[13,14] However, they have yet to be adapted to the unique needs of caregivers of preschool-aged children with NDDs.[14] SSIs are evidenced-based as both a stand-alone service and an immediate support complement to waitlists in existing care systems.

The need for brief interventions that can be widely implemented is both critical and timely. Current waitlists for NDD assessments following pediatrician referral are approximately 12 months in Manitoba, with similar lengths of 6-30 months across Canada.[15] Even after diagnoses, many families wait 6 months for follow-up services, which can result in children aging out of early intervention eligibility at school entry. Creating concrete supports that can be offered to families on NDD waitlists was identified as a key need in the Manitoba Advocate for Children and Youth 2021 "Bridging the Gaps" report to address the right to substantive equality for children with disabilities. Using strategies for patient-oriented research (SPOR), our project represents a first step towards ***the long-term goal of preventing mental illness for children referred for NDDs through an early, scalable, rapidly-deployable intervention.***

Theoretical Foundations

Consistent with the Lagging Skills theory, we propose that impairments in cognitive, emotion regulation, or social skill domains underlie mental health problems in children with NDDs, such that children try to get their needs met in maladaptive ways that are stressful to parents.[11-13] It is common for parents to experience frustration in response to difficult behaviours or emotional expressions and react in harsh ways in an effort to control the situation. However, such interaction difficulties fail to support child skill development and can worsen mental health problems by increasing children's emotional distress.[16] Psychosocial stressors contribute to child mental illness by limiting parents' capacity to provide warm, responsive caregiving important for optimal development and contributing to household instability.[17] Although specific NDD symptoms vary, many child mental health problems stem from common themes of underdeveloped skills and a mismatch with parental expectations. However, there is also a shared opportunity to prevent mental illness by empowering parents to understand *why* children

develop behavioral and emotional problems and *how* to create a supportive environment. Parents can learn to help children develop skills to meet their unique needs, leading to positive child mental health and parenting relationships.[18,19]

Aims and Hypotheses

The objective of this study is to assess the feasibility and acceptability of an SSI (i.e., SPYKids) for parents on local Manitoban service and program waitlists who have children with health, behavioural, and developmental needs. This objective will be divided into Primary and Secondary outcomes.

1. Primary Outcomes: [FEASIBILTY & ACCEPTABILITY]:

Primary outcomes are aimed at determining the feasibility and acceptability of SPYKids compared to SAU. This will be done through monitoring of both clinical coach adherence to protocols via a fidelity checklist and parent satisfaction of the overall SSI via feedback questionnaires including both scaled responses and open-ended responses, using both quantitative and qualitative methodology. Parent feedback of the SSI will be assessed using the Program Feedback Scale[20] (adapted from Dr. Schleider's research), and the feedback questionnaire, which was created by researchers in the lab for the purposes of this study. Please see the attached Appendix C for all questionnaires.

2. Secondary Outcomes:

Secondary outcomes include metrics of parenting stress and mental health between the SPYKids and SAU groups before and after the SPYKids session. Other exploratory outcomes will include both parent and child well-being.

- Parent well-being: Secondary outcomes related to parent well-being will be changes in parenting stress (Parenting Stress Index[21]) and parent mental health

(Patient Health Questionnaire-9[22], Generalized Anxiety Disorder – 7 item scale[23], PROMIS Anger - Short Form[24]). Exploratory outcomes include changes in hope (Beck Hopelessness Scale-4[25]), Perceived control/agency[26], Readiness to change (Readiness Ruler[27]), and Problem Solving[26].

- Child well-being: Primary analyses will compare changes in child well-being scores (Strengths & Difficulties Questionnaire[28]) between the SPYKids vs SAU groups. Secondary analyses will examine persistence of these effects at the 3-month follow-up.

Research Methods

Participants

We plan to recruit 70-140 participants and hope to randomize 70 participants to either the SAU or SSI groups (n= 35 per condition). In order to be eligible to participate, they must have a residence in Manitoba, be at least 18 years old, must identify as a primary caregiver to a child who is 2-5 years old, and the child must be on a waitlist for Neurodevelopmental Services in Manitoba (See Eligibility Screener in Appendix C).

Design & Study Procedures

Recruitment. Participants will be recruited through our established partnership with the Neurodevelopmental Service clinics at SSCY Centre, including the Child Development Clinic and Manitoba FASD Centre. Individuals identifying as primary caregivers to children with additional health, developmental or behavioural needs will be invited via the SSCY "consent to contact" process and/or via social media postings (see attached social media infographic examples in Appendix A). Social media postings will be posted across Hearts & Minds Lab accounts (See Appendix A). Additionally, we will also be asking participants to share our study

and contact information with other prospective participants so that prospective participants can contact us if interested. There will be clear communication to ensure that families understand that project participation will not affect their other services at SSCY. In addition to SSCY we plan to reach out to other local Manitoba organizations (St.Amant, KIDTHINK, MATC) to recruit through their processes after approval is gained.

Consent. Recruited parents/caregivers will click on a link to take part in the eligibility screener via REDCap (sent out via email with recruitment information from the local Manitoba organization, or in response to email correspondence from potential participants from social media postings). When participants click on the link for the eligibility screener, they will see the consent form first, and will be required to click "agree" or "disagree" to consent prior to starting the survey on REDCap. When eligible participants are redirected from the eligibility screener to the pre-questionnaire, they will first see a more detailed study specific consent form at the start of the online pre-questionnaire. This consent form will also be provided at the start of the follow-up and post-questionnaires. This consent form will be attached to the first page of the online REDCap survey. Participants will read the consent form and will respond to it with the click of a button to indicate if they would like to "agree" or "decline" to participate. They may also decline to participate by simply closing the browser prior to starting or at any point throughout the survey. Additionally, consent will also be discussed at the start of the session for participants randomized to the SSI group.

Participant Involvement in Study. For a flowchart of participant contact points please see attachment 'SPYKids Points of Contact' in Appendix D. After completing the online eligibility screener, those who are ineligible will also be automatically sent a compassionate email via REDCap informing them that they are not eligible, with a resource list of mental

health, crisis, and parenting resources. Contact information for the research team will also be included should they have any questions regarding eligibility. Participants who are eligible will be informed via REDCap and automatically sent to the pre-questionnaire. Participants will be screened using questions (e.g., “Are you currently on a waitlist for accessing services for your child?”). Please see Appendix C for REDCap the Eligibility Screener.

Quick Summary of Participant Contact Points if eligible (N=70):

1. Participants will read the main program consent form.

2. If they agree to consent, participants will begin the online pre-questionnaires.

3. Following the pre-questionnaires participants will be randomized to either SAU or SSI group via ID# using an online tool (randomizer.org) and will be notified via email of what group they have been randomized to.

4. Participants randomized to the SSI Group (n=35) will take part in the 90-minute SSI via telehealth, the post-questionnaires immediately post intervention and the 2 follow up questionnaires (2 weeks after the SSI and 3 months after the pre-questionnaire) to assess maintenance effects. Immediately following randomization, participants will be sent an email with an invitation to book a time for the SSI using Microsoft Bookings, a University of Manitoba App part of the Microsoft 365 suite of apps. Participants in this group will also receive a follow-up email from the clinical coach 1-week following the SSI.

5. Participants randomized to the SAU group (n=35) will receive services as usual on the SCCY waitlist, as well as receive a list of psychological and family support services. They will also participate in the eligibility screener, pre-questionnaires, the 2-week post questionnaires, and 3-month post follow-up questionnaires.

Further Details on Project Components:

SPYKids Consultation (SSI) (n=35): Within the pre-questionnaire, a family needs assessment via REDCap will identify parent areas of primary concern across child mental health and psychosocial resource needs (Appendix C). An MA-level trainee (supervised) or PhD-level trainee with clinical experience will review a summary of needs compiled by the project coordinator and then meet with the family in a 1.5-hour session. Sessions will be tailored to identified needs based on materials developed with the parent advisory panel, service providers, and the research team. Content will include psychoeducation, identification of 1-2 skills to address a primary mental health issue, brief practice of the skills, and specific plan to apply the skills at home to obtain a quantifiable reduction in symptom frequency over time. This will be done utilizing handouts created via our research team and guided/reviewed by clinical psychologists (Drs. Leslie Roos and Emily Cameron) to employ best-practices in promoting positive parent-child relationships and reducing parenting stress (See Appendix D). Lastly, families will be provided with specific recommendations for relevant services and informal supports from our family-focused resource list (Appendix D). As mentioned above, the purpose of the SSI is not to completely resolve challenges, but to provide parents with some help, encouragement, and motivation in the interim while waiting for other services. Around one week after participants attend the single session, they will receive a customized email summarizing what was discussed during the session by the clinical coach to build motivation (informed by Dr. Schleider's methodology).

The study will take place online, through Zoom Healthcare, REDCap, and through emailing with the research team and community organizations regarding support with recruitment procedures. Recruitment may take place at a variety of community-based services through postering, through email listservs, or talks by the research team.

The time commitment is approximately 3 hours for the SSI program group, and 1 hour for the SAU group. Participants in the SSI group will fill out a brief online screener (2 minutes), a pre-session questionnaire (30 minutes), attend the 90-minute single session, fill out a post-session questionnaire (15 minutes), and then the two follow-up surveys (20 minutes each). Participants in the SAU group will also complete the brief online screener (2 minutes) and the pre-session questionnaire (30 minutes). After randomization, they will only complete the two follow-up surveys (20 minutes each).

Honorarium. Participants in both groups will receive up to $75 in Amazon e-gift cards for their participation. Participants will be compensated at certain steps of the research project following the SSI (or pre-questionnaires for the SAU group) to encourage continued interest and participation, given that the project takes place over a longer period of time, and to compensate already busy parents for their time. Notably this compensation is designed to compensate time for assessments (questionnaires) only, but not the intervention time. Due to randomization both the SAU and the SSI group will receive the same $75 compensation in the form of e-gift cards for participating. Participants in the SSI group condition will receive $25 e-gift cards after taking the following questionnaires: the post-session questionnaires (which follows the pre-session questionnaires and SSI Zoom session) and after each of the two follow-up questionnaires (at 2 weeks and 3 months after the session). Participants in the SAU condition will complete the pre-questionnaire and after randomization will receive a $25 dollar e-gift card to parallel the $25 e-gift card received by the SSI group. Consistent with the SSI group, they will receive a $25 e-gift card after each follow up questionnaire is completed (1 month and 3 months after pre-questionnaire) for a total of up to $75 gift card for participating.

Participant Withdrawal. As soon as participants finish a step in the study outlined above to receive compensation, or start a step and then decline to continue, they will be emailed with a gift card code to claim their compensation. However, should participants choose to withdraw during completion of the questionnaires, it may be unclear if the participant is officially withdrawing or taking a break from the survey. As the survey is designed to allow for participants to return and complete unfinished questions at a later date, withdrawal will not be obvious. As such, the consent form outlines that should participants wish to withdraw while in the process of completing the questionnaires, they can notify the researchers through email to receive the e-gift card for their participation up to that point. The consent form clearly states that there are no consequences to participant withdrawal.

Measures

Please see Appendix C for a table of questionnaires, and copies of all questionnaires.

Data Collection & Management

Due to the nature of the single-session consultation pilot there is no way to make participation anonymous to the researchers, as participants will meet with the researchers via Zoom Healthcare. Participants will enter identifying information only on the eligibility screener (e.g., name, email address) and booking system (Microsoft Bookings). Only the PIs, project coordinators, and lab coordinator will have access to the surveys. Directly identifying information will be kept on a password protected file on the University of Manitoba's OneDrive. The project coordinator will send password protected files to clinical coaches prior to each session containing relevant information (e.g., participant name, participant email so clinical coach can send a follow-up). Clinical coaches (or research staff) will state that everything shared

within the 90-minute SSI will be kept confidential between the acting clinical coach and the participant with exceptions to concerns regarding the safety of the participant or others.

Questionnaires will be completed through the online REDCap portal. This information will be stored on the secure REDCap survey server maintained by MedIT of the Max Rady College of Medicine. Only the principal investigator, project coordinator, and a select few trusted research assistants will have login access to the survey responses on REDCap. Directly identifiable data (questionnaires, booking system, SSI Zoom session), anonymized data (open-ended responses that are edited to remove identifiable data), and de-identified data (all data will eventually be moved to the Secure Research Environment and responses will only be linked to de-identified numbers) will be collected. This information will be stored on the secure REDCap survey server maintained by MedIT of the Max Rady College of Medicine. Only the principal investigator, project coordinator, and a select few trusted research assistants will have login access to the survey responses on REDCap.

Anonymized data will be stored on password protected lab computers only accessible by research staff. Once data collection is complete, it will be moved to the Secure Research Environment after randomization; when downloaded, all identifying information will be removed. This plan aligns with the University of Manitoba's REDCap policies. All identifiable information (except full names as stated on consent forms) will be deleted after data collection is complete and study results have been distributed to participants. Anonymous survey data will be kept until 09/2027. It may be archived for future analyses, but since responses are completely anonymous there is no risk involved in storing this data long term. Directly identifiable data (e.g., name, email addresses) will be destroyed upon project completion (September 2023). Summary statistics (e.g., questionnaire subscales) may be shared on data repositories such as the

open science framework, and this is outlined in the consent forms. Birth dates will be converted into age in months and all information about birth date will be destroyed afterward. De-identified data will be stored on REDCap's Secure Research Environment and kept for an indefinite amount of time, as we cannot anticipate all possible future analyses that might be theoretically or practically useful.

Other Data Collected. Participant ID keys will also be created. Participant ID keys will be directly identifiable. Participant ID keys will consist of participant emails, first names, and the de-identified number. This data will be directly identifiable. The participant ID keys will be saved on a password protected file on the University of Manitoba Onedrive. Only the PI, the project coordinators, and lab coordinator, will have access to this. This data will be destroyed upon project completion (expected September 2023).

Additionally, a contact list for those that wish to receive a summary of research findings will be created. The survey may be directly identifiable on REDCap, as it will be linked to the participants email address, depending on whether or not a participant's email address contains their name or other identifying information. This data will be collected in the pre-questionnaire portion of the study. After completing the pre-questionnaires, participants will be redirected to a separate REDCap project, and will be asked if they would like to receive summary statistics, and if so, they will enter their email. Once recruitment is completed, this project will be moved to the Secure Research Environment in REDCap. We will delete these emails once we are finished with planned analyses and have emailed the results to interested participants. Of note, while some study findings may be published as early as September 2023 from baseline data, future research on exploratory outcomes may take several years to complete. We plan to send out

results on an annual basis until all planned studies are complete, at which point, the email list will be permanently deleted. This is reflected in the consent forms.

Another contact list will be created for those that wish to be contacted for future studies. The survey may be directly identifiable on REDCap, as it will be linked to the participants email address, depending on whether or not a participant's email address contains their name or other identifying information. This data will be collected in the pre-questionnaire portion of the study. After completing the pre-questionnaires, participants will be redirected to a separate REDCap project, and will be asked if they would like to be contacted for future studies, and if so, they will enter their email. Once recruitment is completed, this project will be moved to the Secure Research Environment in REDCap. These emails will be stored indefinitely on the SRE. If participants contact us to remove their name from this list, we will permanently delete their contact information from the SRE.

Online consent forms will collect participant full name and email addresses and therefore be directly identifiable. The REDCap Project containing the consent forms does not contain any PHI (all questionnaires are housed in a different project), in line with the University of Manitoba's REDCap policies. This information will be stored securely on REDCap servers. They will be transferred from the REDCap Survey server and transferred the Secure Research Environment upon completion of recruitment. Consent forms will be stored on the Secure Research Environment for the expected duration of the project and its publications, in case of an audit. They will be destroyed by (09/2027). These will not be physical paper copies, but digital copies.

In general, de-identified data will be password-protected and stored on OneDrive and shared with team members in the Hearts & Minds Lab via their University of Manitoba emails.

De-identified data (e.g., standardized questionnaire responses, aggregated program use data, sociodemographics linked to an ID number) may be made available on public data platforms such as open science framework or a requirement by a granting agency or journal, or to our partners outside of the University of Manitoba (i.e., Dr. J. Schleider).

Statistical Analyses

Across all self-report questionnaire outcomes, measures have excellent reliability and validity. This includes established cut-offs indicating mental health problem severity needs therapeutic services with high sensitivity/specificity to diagnostic interviews. Constructs with established tools from consortium agreements, per the COMET (Core Outcome Measures in Effectiveness Trials) Initiative are prioritized.[29]

Primary outcome. Child mental health. The primary analyses will compare the change in child mental health symptom scores between (a) the SPYKids vs SAU group at p=0.05 using a linear model for the change, accounting for pre-intervention scores and important covariate of child age. Secondary analyses will examine persistence of these effects at the 3-month-follow-up by examining the time-by-intervention interactions in a linear mixed-effects model accounting for within-subject serial correlations, and between-subject effects of the intervention and age.

Secondary outcomes. Parenting stress & mental health. We will use similar linear mixed-effects models for the analysis of key secondary outcomes.

Exploratory outcomes. Parent Self-Efficacy. Exploratory analyses (SPYKids only) will assess the extent to which dimensions of parenting self-efficacy (hope,[25] agency,[26] readiness to change[27]) immediately following the intervention are associated with primary and secondary change. This will inform how immediate post-treatment progress in linked to subsequent improvements in well-being. Parent Satisfaction will be assessed to determine if key benchmark

acceptability is met 3.5/5 on an established scale.[20] Participants will complete open-ended text-based items allowing them to express their views on the intervention content, their engagement with this content, their satisfaction with their involvement in the intervention, and suggested improvements. Open-ended text items will be analyzed using thematic analysis.[30]

General considerations. In general, p-values < .05 will be considered statistically significant, without controlling for multiple inference. Complete-case methods will be used for planned analyses; however, sensitivity analyses may be used to examine the impacts of imputation on conclusions, should the usual assumptions appear to be met (MAR, missing at random, or MCAR, missing completely at random). Data will be stored in REDCap following Good Clinical Practices.[31] Analyses will be done in R v.4.0.0 and the lme4 package v 1.1-26.35

Knowledge Translation

Broadly, as mentioned in the SSCY Research Access Application Form, the results of this study may be disseminated through the Family Advisory Council, the Family Network Newsletter, reports to service providers at SSCY, theses, journal articles, conference publications, and reports to funding agencies. Study participants will be able to indicate if they would like to be emailed the results of the survey. Interested participants will receive an email that summarizes the results in lay language and using infographics no later than September 2023. We would be glad to coordinate additional KT avenues with the Research Development Coordinator as useful to the teams at SCCY (e.g., Breakfast at SCCY learning series session).

Timeline & Budget

We plan to begin recruitment for the SPYKids pilot in November 2022. Sessions will run from November 2022 until approximately February 2023 based on recruitment success. Data analyses and knowledge translation will occur soon thereafter.

In terms of our budget, we have $10, 500 for participant honorariums (up to 140 participants, being paid up to $75 each). We also have $254 for printing, envelopes, and stamps. Other expenses (e.g., research assistant salaries, paid Zoom Healthcare account) are being paid through other grants and funding, such as the Graduate Enhancement of Tri-Agency Stipends Program. No other expenses are expected, as all other communication during the program will be via email.

Implications

SPYKids offers a unique opportunity for a brief early intervention in families of children with emergent NDDs. This is significant because it provides an immediate service up to 18 months earlier in child development to (a) decrease the ultimate need for services by preventing severe mental health problems and (b) increase uptake and perceived effectiveness of subsequent NDD treatment. SPYKids has widespread impact potential for promoting child mental health through cost-effective programming designed to scale across contexts. These services are expected to be particularly important in the aftermath of COVID-19 in which lockdowns and reduced services have increase mental health problems in children with NDDs.[32] Our work is closely aligned with calls from global leaders, including UNICEF and The World Health Organization, to address family distress to promote child health, as well as the Children's First Canada's 2020 report, which identifies child mental illness as the #2 threat to well-being.[33]

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