Strongest Families FASD: Parent training for challenging behaviour in children with Fetal Alcohol Spectrum Disorder (FASD)

Study Protocol

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**Background and Rationale**

Prenatal alcohol (ethanol) exposure is the leading known cause of developmental disability in Canada and is the most prevalent preventable cause of congenital neurobehavioral dysfunction in the Western world (1). Despite attempts to increase public awareness of the risks associated with drinking during pregnancy, a significant proportion (>6%) of pregnancies in Canada are alcohol-exposed (2). The term Fetal Alcohol Syndrome (FAS) was introduced over 30 years ago (3-5) as a diagnosis for children who exhibit the triad of central nervous system (CNS) dysfunction, growth deficiency, and characteristic craniofacial dysmorphology resulting from maternal consumption of excessive amounts of alcohol during pregnancy. Of these features, it is the CNS injury that is most debilitating and can manifest as intellectual, neurological, and behavioral abnormalities. Recently, the term Fetal Alcohol Spectrum Disorder (FASD) was established to encompass the full spectrum of teratogenic effects induced by ethanol (6). FAS is believed to occur in approximately 1 to 3 per 1000 live births in North America and it is estimated that FASD may occur as frequently as 1 in 100 live births (7); although recent epidemiological studies suggest prevalence rates as high as 2-5% (8). Recently, the total adjusted annual cost associated with FASD in Canada was estimated at $5.3 billion (9), further illustrating the substantial cost of FASD to Canadian families and the need to make positive changes.

Although considerable efforts have been made at providing diagnoses for children with FASD, the need for services and supports remains unmet (10). Parents, who care for children with FASD, are often confronted with significant behavioural challenges without resources and information to manage these symptoms. Problems with service delivery are further compounded in rural communities, where access to specialized healthcare programs is extremely limited. Even when treatment is available, significant barriers such as the costs associated with travelling to clinics for repeated consultations and time spent away from work, make it difficult for families to benefit from them.

The Strongest Families FASD program was designed to address many of these issues by providing distance healthcare services to families with children exhibiting mild to moderate behavioural problems. Parents work online through a progressive curriculum that includes exercises, instructional videos, and they participate in weekly telephone sessions with a trained coach. Although the coach is not a clinician, they have undergone extensive training at the SFI and are highly skilled to provide support, respond to questions and concerns, and discuss the program content.

A key goal of the Public Health Agency of Canada’s (PHAC) FASD initiative is to increase capacity to identify and meet the needs of children, youth, adults, and families affected by FASD. Despite a variety of psychosocial interventions aimed at supporting individuals with neurobehavioral disorders, relatively little research exists that is specifically aimed at improving the behavioural challenges associated with FASD (11). The goal of this project is to conduct a RCT that will evaluate the Strongest Families FASD program that is designed for families who have children between the ages of 4-12 years with FASD.
**Research Question**

**GOALS:**

1) To test the feasibility of the Strongest Families FASD.
2) To evaluate the efficacy of Strongest Families FASD in reducing externalizing problems [primary outcome], internalizing problems, and parental distress [secondary outcome] in children aged between 4 and 12 years diagnosed with FASD at 5 and 11 months post-randomization when compared to an online psychoeducation control.
3) To evaluate the efficacy of Strongest Families FASD in improving social competence [secondary outcome] in children aged between 6 and 12 diagnosed with FASD at 5 and 11 months post-randomization when compared to an online psychoeducation control.

**HYPOTHESIS**

No hypotheses posited for goal #1.

We hypothesize that the effects of Strongest Families FASD on externalizing problems measured by CBCL Externalizing Scale, internalizing problems measured by CBCL Internalizing Scale, parental distress as measured by DASS-21 and social competence as measured by CBCL Competence Scale will be significantly greater than that for the control group over the 11-month follow up period.

**Research Design and Methodology**

**Study design**

This study is a two-arm Randomized Control Trial (RCT) comparing groups assigned to receive either an Internet-based parent-training program (SF Intervention Group) or a static resource webpage (Control Group). The Consolidated Standards of Reporting Trials (CONSORT) recommendations (http://www.consort-statement.org/) will be used to guide the methodology.

**Participants**

A sample of 200 parents/caregivers of children with FASD, aged 4-12 years, will be recruited into the study through our collaboration with Dr. James Reynolds’ lab at Queen’s University.

**Measures**

The Child Behaviour Checklist (CBCL) and Depression Anxiety Stress Scale (DASS-21) will be administered to all participants at Baseline (pre-randomization), 5 months and 11 months post-randomization. The Client Satisfaction Questionnaire (CSQ-8) and Strongest Families Program Satisfaction Questionnaire: FASD Version will be administered only to the Intervention Group upon completion of the program.
Primary Outcome Measure

The Child Behavior Checklist is a standardized questionnaire that assesses adaptive functioning and problems (12). We will use two versions of the CBCL (CBCL/1 ½ -5 and CBCL/6-18) to accommodate the age range of the sample. Scores for each of the behaviour scales are rated as “clinical” or “borderline clinical” based on the T-scores. Because the CBCL is among the most widely used measures in children’s mental health research, this will allow us to compare our findings to those of obtained by other investigators. It is demonstrably sensitive to the effects of parent training programs. The CBCL requires 15-20 minutes to complete and has been adapted for administration using the IRIS platform.

CBCL/1.5-5 (Appendix B-3). The CBCL/1 ½-5 consists of seven syndrome scales (Emotionally Reactive, Anxious/Depressed, Somatic Complaints, Withdrawn, Sleep Problems, Attention Problems, Aggressive Behaviour). Attention Problems and Aggressive Behaviour group into an Externalizing Factor. There are no DSM or competency scales for this version.

CBCL/6-18 (Appendix B-4). The CBCL/6-18 consists of eight syndrome scales (Anxious/Depressed, Withdrawn/Depressed, Somatic Complaints, Social Problems, Thought Problems, Attention Problems, Rule-breaking Behaviour and Aggressive Behaviour), which group into two higher order factors: internalizing and externalizing behaviours. Six Diagnostic and Statistical Manual (DSM)-oriented scales consistent with DSM diagnostic categories (affective problems, anxiety problems, somatic problems, ADHD, oppositional defiant problem, conduct problems) are evaluated. The CBCL also provides competence scales for activities, social relations, school and total competence. Internal consistency for the CBCL Externalizing scale is 0.94, 8-day test-retest reliability was 0.92, and stability over two years was 0.82.

Secondary Outcome Measures

The Depression Anxiety & Stress Scale Short Form (DASS-21) (Appendix B-5) will be used to evaluate parental distress. The DASS-21 consists of three subscales (depression, anxiety and stress) that can be combined into a composite measure of general distress (13). The DASS-21 demonstrates strong internal consistency with alpha values .84 for Anxiety, .90 for Stress and .91 for Depression. The DASS-21 has proven sensitive to the effects of parenting interventions and requires 5-10 minutes to complete.

Satisfaction Measures (Intervention Group only*):

Client Satisfaction Questionnaire (CSQ-8) (Appendix B-6) has been widely used in primary care and mental health treatment to measure patient/client satisfaction with services received (14). Participants will be asked to rate the quality of service they received as part of the Strongest Families FASD Program on a 4-point scale. Internal consistency for the CSQ-8 is reported with Chronbach’s alphas ranging from .83 to .93 (15).
**Strongest Families Program Satisfaction Questionnaire: FASD Version** (Appendix B-7) asks participants to rate (on a 5-point scale) their agreement with statements about the Strongest Families Program specific to Parenting, Coaching, Program Components (written materials, videos, etc.), and the Website. The psychometric properties of this tool have not been tested.

*NOTE:* The Satisfaction Measures will also be available to participants from the Control group who choose to access the online materials (without coaching) offered after their study participation is complete. Responses to the Satisfaction Measures from Control Group may be examined as a sub-study of the current application to inform future research and/or program development. Honoraria will not be provided for Satisfaction Questionnaires submitted by former participants of the Control Group.

**Methods**

**Recruitment**

The recruitment strategy for this study will be broadly based across Canada using an existing database, referrals from FASD clinics and service providers, and general advertising. All interested individuals will be directed to a Study Recruitment Website (described below) to receive study information, to screen for eligibility and to complete online consent (if eligible). Advertisement materials (poster, brochure and sample web ad), recruitment email and telephone script are attached (Appendix A-1 to A-4). Social media posts (e.g. facebook, twitter, LinkedIn) samples are shown in Appendix A-10. Text for social media posts will change frequently to maintain interest in the study, encourage “sharing” and extend recruitment reach. Posts may include, for example, study updates, de-identified testimonials from study participants (with participant express email consent), FASD information.

**Database**

The Reynolds lab maintains a database of former study participants, many with FASD, who have agreed to be contacted for future research opportunities. Our colleagues at Queen’s University will contact members of this Canada-wide database who meet the inclusion criteria for age and FASD diagnosis.

- If the database includes an email address, a study information email will be sent introducing the study and including a link to the study recruitment website (MyStudies).
- If the database does not include their email, a research associate will call to let the person know they may be eligible to take part in a study for FASD. If the individual is interested, a research associate will collect an email address and send a study information email with the link to the study recruitment website (MyStudies).
**Referrals**

Our collaborators at Queen’s University have established partnerships with FASD clinics and support programs across Canada. These organizations will be approached to refer potential eligible individuals to the study. Study staff will not receive contact information for third parties. All individuals will be directed to the study recruitment website (MyStudies).

**General Advertising**

Advertisement materials (e.g. posters, brochures, web ads, videos and social media posts) will be distributed electronically and/or in paper format to potential study participants via appropriate venues within Canada. Appropriate venues are those places (online or physical with relevance to FASD information, diagnosis, treatment or other support. These may include, for example, hospitals, physician's offices, diagnostic and treatment clinics, service providers support groups, schools, conferences or websites. All advertising materials will direct interested individuals to the study recruitment website (MyStudies).

**Screening for Eligibility**

Screening for Eligibility and Consent will be conducted using an online recruitment site MyStudies.ca. MyStudies.ca is run by Connec (http://connec.ca/) housed at the Centre for Research in Family Health. A series of sample screen shots starting with the study landing page and ending with the digital signature box is attached showing how the participant will be guided step-by-step through the enrolment process (Appendix A-5). Electronic data captured in MyStudies will be stored on a secure server managed by Canadian Web Hosting, whose servers and processes regularly undergo security audits. MyStudies has been approved by the REB for screening and consent for the Breathe Anxiety Study (REB #1015715).

Individuals who visit the study recruitment website will receive a brief description of the study at the landing page. Appendix A-6 shows the text which will be visible at the landing page, however the software is in development and the final format will look like the sample landing page shown in Appendix A-5. Here they will indicate whether they are a potential study participant or whether they wish to provide Authorization for a participant.

Potential participants will be invited to complete online Screening for Eligibility (see Inclusion/Exclusion Criteria below and Appendix A-7). Individuals may request (via the website) contact with study staff if they would like to speak to someone about the study. Answers to the eligibility questions will be automatically assessed by MyStudies and individuals will immediately receive an online message stating whether they are eligible or ineligible to continue. Individuals who are eligible at Screening will be invited to proceed to online Consent, also within the MyStudies site.
Individuals visiting the site to provide (or deny) Authorization will follow another path through MyStudies, described below.

**Screening Inclusion Criteria**

Parents/caregivers must meet all of the following criteria to be eligible to proceed to Consent:

a. Have a child between 4-12 years of age with a diagnosis under the umbrella term Fetal Alcohol Spectrum Disorder as reported by parents/caregivers.
b. The child has been experiencing behavioural problems (as defined by the caregiver) for at least 6 months prior to study screening.
c. Have been the primary caregiver for a minimum of 6 months prior to entry into the study.
d. Have a reasonable expectation of being be the primary caregiver for at least 6 months after study enrolment.
e. Read, write, and understand English.
f. Have access to a telephone.
g. Have access to a computer connected to the Internet.
h. Live in Canada.

The age range for the sample was chosen because interventions provided at this stage can help to prevent the development of secondary problems and parent-training methods have been most highly developed for this age group (16). We would like behaviour problems and the caregiver’s experience with the child’s behaviors to be stable over time (minimum 6 months) to facilitate the demonstration of changes in response to treatment. We have set the geographic region for study participation to Canada at this time. The remaining criteria are necessary to accommodate delivery of the program.

**Screening Exclusion Criteria**

Any of the following criteria will exclude individuals from proceeding to Consent:

a. Child is NOT able to speak in full sentences or understand everyday language and instructions.
b. Parent has previously taken part in a Strongest Families Parenting Program.
c. Parent OR child has been diagnosed with psychosis.
d. Child has been diagnosed with schizophrenia, bipolar disorder or major depression.
e. Child puts others at risk of serious harm (i.e. requiring hospitalization or medical attention).
f. Parent has taken part in Triple P, COPE, or Incredible Years parenting program within 6 months prior to starting the study.
The nature of the intervention program requires that the child be able to communicate and understand everyday language and instructions. Criterion “a” is an effort to safeguard against the risk of enrolling individuals for whom the intervention is not appropriate.

Those who have previously completed the Strongest Families Parenting Program won’t be eligible because for these cases SFI provides a refresher. That is, they build on their strengths learned during their previous experience with the SFI and they often do not follow the full program as they do with the new cases.

Parents/caregivers who have completed a parenting program which teaches skills similar to those in the current intervention (i.e. Triple P, Incredible Years or COPE) will be ineligible for study participation if they have completed the program within 6 months of starting the study as we would not be able to discern whether a change in the child’s behaviour is an effect of the Strongest Families intervention or an effect of another parenting program. Requiring a minimum 6 months waiting period after completing a similar parenting program will increase confidence that the previous parenting program has been ineffective and any changes in the child’s behaviour is more likely to be attributed to the current intervention. A diagnosis of psychosis for either the child or parent or a diagnosis of a major mental health disorder for the child represents a complexity which is not suitable for mild to moderate behaviour problems for which the intervention program is designed.

Consent Phase

Individuals who meet all Screening criteria and none of the Exclusion criteria will be invited to proceed to the online Consent Form (Appendix A-8). The online Consent process is interactive; individuals will be asked to answer true/false questions after each section of the Consent Form acknowledging an understanding of study participation. A “Contact Us” button will be situated on each page of the Consent Form providing individuals the opportunity to request a telephone call from research staff to answer any questions they may have about the study. A copy of a blank Consent Form may be downloaded in PDF format from the MyStudies website.

Individuals will be introduced to a Feasibility Sub-study (described below) during Consent. This will be presented as optional to the main study (i.e. participants who agree to the main study may opt in or out of the Feasibility study). Individuals may agree to participate in one or both parts of the study by submitting the completed Consent Form or may decline participation at anytime. Participants will receive email confirmation of their Consent (including date and time Consent was given) and a PDF copy of the Consent Form for their records. The participant will also receive a separate email containing their unique IRIS* user ID and password and prompting them to log into IRIS to complete Demographics (Appendix B-1) and Baseline Questionnaires (Appendices B3 or B4 and B-5).

Primary caregivers who are NOT legal guardians (e.g. foster parents, relatives) of the child to whom the study pertains will be required to obtain Authorization (Appendix A-9) from the child’s legal guardian before taking part in the study. Caregivers who have self-identified during the Screening process as not being a legal guardian will be automatically notified in MyStudies.
that authorization will be required from the child’s legal guardian in order to proceed. Those interested in continuing will be permitted to complete Consent. Upon submission of a completed Consent Form, the participant will receive an email containing an attached PDF copy of the complete Consent Form with instructions to forward to the legal guardian requesting Authorization. The forwarded email will contain a code used to link the Consent and Authorization Forms and will direct the legal guardian to the MyStudies site. The authorizer will be provided a brief description of the study, will be able to review the full blank and/or completed version of the Consent Form and provide (or deny) Authorization. Those who provide Authorization will receive an email confirming their Authorization (date/time), copied to the study participant with a PDF of the participant Consent Form attached to the Authorization Form as one document. Study participants will receive email notification if they have been declined Authorization.

Individuals who Consent to study participation but are unable to gain necessary Authorization will not be permitted to complete baseline questionnaires and will be notified promptly of their withdrawal from study participation.

*Note: IRIS (Interactive Research and Intervention Software) is the electronic information system that will be used to conduct this RCT and to deliver the Strongest Families FASD program. IRIS is a web-based architecture that has been developed in house and is currently used by other studies approved by the IWK Ethics Board (REB #1015715).

Recruitment Survey

In order to assess the effectiveness of our recruitment strategy we will ask participants where they heard about the study. A checklist of options will be offered after Consent in the myStudies recruitment site (Appendix A-11).

Baseline Phase

The Baseline Assessment will determine a participant’s eligibility to be randomized into a study group. Those not meeting eligibility will be withdrawn from study participation. All participants who complete the Baseline Assessment will receive a $25 gift card by mail or email (their choice). *Note: DASS scores will not be used to determine eligibility.*

Baseline Inclusion/Exclusion Criteria

Participants must meet all of the following criteria:

1) CBCL Externalizing t-Score must be ≥64 (borderline clinical/clinical range)
2) Meets criteria for behaviour suggestive of FASD
3) No suicide attempts within the previous 6 months*
4) No current risk of suicide attempts*
5) Diagnosis conforms to recognized diagnostic scheme
*NOTE: (CBCL 6-18 only) Risk management procedure for endorsement of suicide attempts or current risk of suicide are detailed below under Monitoring for Safety During Study Activities (IWK/Queen’s).

Upon logging into IRIS, participants will be prompted to complete a Demographics Form (Appendix B-1), CBCL and DASS questionnaires (Appendices B-3 to B-5) (approximately 20-30 minutes total).

Responses to the CBCL will determine eligibility for randomization:

1. The CBCL will be scored by study staff using licensed scoring software to determine Externalizing Scale t-score.

2. a. For children age 6-12 (6-18 CBCL) participants must endorse 7/8 items listed below.

   b. For children age 4-5 (1 ½ - 5 CBCL) participants must endorse 3/5 of the items listed below with at least two endorsements from the items marked with an asterisk.

<table>
<thead>
<tr>
<th>CBCL Item</th>
<th>1 ½ -5 CBCL</th>
<th>6 – 18 CBCL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acts young for age</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>*Can’t concentrate or poor attention</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>*Can’t sit still, restless, hyperactive</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>*Disobedient at home</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Doesn’t show guilt after misbehaving</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Argues a lot</td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Impulsive or acts without thinking</td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Lying or cheating</td>
<td></td>
<td>✔</td>
</tr>
</tbody>
</table>

3/4. Criteria 3 & 4 above will be screened for using the CBCL/6-18 only. Endorsement of item 18 (Deliberately harms self or attempts suicide) will generate automatic probes for details within IRIS. (See section Monitoring for Safety During Study Activities (IWK/Queen’s) below for details.)

5. Diagnosis will be reviewed manually to ensure that it matches one of those listed in Demographics section of the Baseline Assessment or if “other” is endorsed, it will be confirmed by the co-PI (or delegate) that the diagnosis identified (i) has been provided by a recognized FASD diagnostic clinic, and (ii) conforms to one of the recognized diagnostic schemes used in the assessment of children suspected of having an FASD.

Eligibility/Ineligibility will be entered manually into the IRIS system. Participants NOT eligible to be randomized (EXT t-score ≤ 63 or not meeting criteria for behaviour suggestive of FASD) will be withdrawn from the study and will receive a Baseline Withdrawal (Exclusion) Message (Appendix D-1) sent to their study email (within IRIS). Participants will be able to request a phone call from study staff to discuss their exclusion from the study. Research staff will follow the Baseline Withdrawal (Exclusion) Telephone Script (Appendix D-2) as a guideline for all phone calls that are requested by individuals who have been withdrawn at baseline.
All participants who are deemed eligible will be randomized.

The diagram below summarizes the Baseline Phase.

**Randomization Phase**

Random allocation to the Intervention or Control group in 1:1 ratio will be carried out independently by an external researcher using a block randomization procedure with random block sizes of 2 and 4. A random numbers sheet for the trial will be first generated (http://www.randomization.com/) and then the random numbers (0=Treatment condition; 1=Control condition) will be put into sealed numbered envelopes by an external researcher. Envelopes will be opened sequentially by the Coordinator (or delegate) and only after the enrolled participants complete the baseline assessments and are deemed eligible to continue.

**Intervention Phase**

The Intervention Phase will differ for participants depending on whether they are randomized to the Intervention Group or to the Control Group. Neither group will be restricted from accessing additional programs or services during study participation. To ensure equipoise, similar study procedures will be applied, except where the procedures are specific to a given group. Special consideration has been made to the content of written participant communications to ensure the language is identical or similar whenever possible.
**Intervention Group**

The principal components of the curriculum of the intervention have been approved in previous studies and are currently being used by the Strongest Families Institute Service Program. However, revisions have been made to the content to customize the intervention for families affected by FASD. The revisions have been informed by data that was collected in a series of telephone interviews with families and clinicians who have personal and professional interest and expertise in the field (REB #1010026).

- The Strongest Families FASD intervention will be delivered over the Internet via a website using IRIS (Interactive Research and Intervention Software). Participants will enter information into IRIS to allow the intervention to be customized with the child’s name and specific behaviour problems.
- The program is comprised of 11 sessions, each focusing on a different parenting strategy, delivered using easy to read text, instructional videos and audio clips. One Booster
Session will be conducted 1 month after completion of Session 11. Please refer to (Appendix C-1) for a summary of the program sessions.

- Participants will receive a package in the mail that includes additional program materials such as a Reward Chart, a Daily Strengths Chart, a Visual Schedule Template and Tryout Pages (Appendices C-2 to C-5).
- A trained non-professional Coach will schedule weekly telephone calls with parent/caregiver to facilitate problem solving and provide support in acquiring parenting skills. The Strongest Families FASD program will be provided to the parent; there will be no contact with the child. Partners or spouses are encouraged to review the Strongest Families materials and to use Strongest Families skills.
- Participants will be encouraged to complete the Strongest Families FASD program at a pace of one session per week. However, based on SFIs extensive experience with similar program delivery, we anticipate that the program will take approximately 5 months to complete.
- Because Strongest Families is a minimal risk education program, an experienced Coach Supervisor (not a licensed health care professional) will provide weekly supervision to Coaches.
- Participants will receive a Mid-Intervention Progress Message (Appendix D-5) and an End Intervention Progress Message (Appendix D-7) summarizing the participant’s progress based on self ratings given at the end of each session.
- An ‘Ask the Experts’ message board (Appendix C-6 with screen shot) feature within IRIS will allow parents to receive answers to individual questions from FASD experts. This information will be available to all participants in the intervention group. The protocol for ‘Ask the Experts’ is provided below.
- A Satisfaction Survey will be offered after Session 11 allowing participants the opportunity to comment on various aspects of the program. The Satisfaction Survey will consist of two measures; the CSQ-8 (Appendix B-6), a standardized measure of client/patient satisfaction, and the Strongest Families Program Satisfaction Questionnaire (Appendix B-7), with questions specific to Strongest Families coaching, program materials and the website.

Ask the Expert Protocol

The Strongest Families FASD program includes an ‘Ask an Expert’ feature, which will allow participants in the Intervention Group to ask questions to FASD experts (see Appendix C-6 for a sample screenshot). Participants will be informed that ‘Ask an Expert’ is an educational tool and that it is not meant as therapy, or as a substitute for professional advice. Participants will be directed to their family doctors for medical concerns and informed that referrals or emergency information cannot be provided based on their questions.

IRIS will send an email to the Content Manager (or delegate) of Ask an Expert feature when a question has been submitted. The Content Manager (or delegate) will relay the question to the appropriate expert who will provide a response within 4 days. A question deemed by the PI (or delegate) to be of potential interest to the larger group will be de-identified and posted to the message board with a response. The author of that question will be notified by email and directed to the message board to view the response. Authors of questions which have already
been answered on the board will be directed to the board to view a similar question and response. Questions which are not appropriate or deemed not of potential interest for the larger group will be answered individually via email to the author’s IRIS inbox. Dr. Hanlon-Dearman and Dr. Christine Looke have agreed act as experts for this feature of the trial. Their CVs have been provided (Appendices E-1 and E-2).

Control Group

- The Control Group will receive access to a static webpage on IRIS providing FASD information and resources, including recommended book titles, websites and organizations that may be helpful (Appendix C-7 partial screenshot).
- Participants in the Control Group will receive a Mid-Study Progress Message (Appendix D-6) approximately 10 weeks after randomization (coinciding with the expected Mid-Intervention Progress Message for the Intervention Group). The message will encourage participants to continue to visit the static webpage and remind them of the 5 Month Follow Up Assessment.
- Participants in the Control Group will gain access to the Strongest Families program (without coaching) after their study participation is complete. Because Strongest Families FASD consists of minimal risk educational material, it is not anticipated that individuals who access the online program will be at risk of any harm by not having access to the coaching component of the program. The program contains built-in tutorials to help users navigate the website and technical support will be available.
- The Strongest Families program will be accessible until 6 months after the last Control Group participant has received access to the website.

Follow Up Assessments (Intervention and Control Groups)

- All participants will receive an email message 5 months and 11 months after randomization, prompting them to complete the Follow-up Assessments.
- Participants will be asked to complete the DASS and the CBCL and to update some demographic information (e.g. child’s medications, any new diagnoses).
- The assessments will take approximately 20-30 minutes in total to complete.
- Upon completion of each Follow-up Assessment, participants will receive a $25 gift card by mail or online and a summary of their assessment results via email (within IRIS) (Appendices D-8 to D-10).
- Study participation ends for participants in both study groups after completing the 11 Month Follow-up Assessment at which time participants in the Control Group will receive access the online Strongest Families FASD program.

Data Analysis

Data will be analyzed by a statistician blinded to group assignment. The primary outcome variable will be change in behaviour of the children as indicated by the Externalizing Scale of the
Child Behavior Checklist (CBCL). The secondary outcome variable will be the well being of the responding parent as evaluated using the Depression Anxiety Stress Scales (DASS-21). The design can be viewed as a 2 (group) x 3 time (baseline, 5months, 11 months) mixed factorial with repeated measures on the time factor.

If data sets are complete, an independent samples t-test will be employed to compare the group differences. However, not all patients will complete treatment (attrition) therefore to include all randomized patients in the analysis and to meet the intent-to-treat principles, we anticipate using a full information maximum likelihood (FIML) mixed-effects regression framework for the analysis. Specially, we will create a hierarchical (“stacked”) data set and regress the CBCL scores on group (dummy coded as Control=0 and Treatment=1), time (coded naturally as baseline=0, 5 months=5, etc.) and the group x time interaction. Additional covariates will be added to the model as warranted. The critical test will be the group x time interaction. Based on the described coding, the parameter for this effect will be the estimated differential change on the CBCL between the control and treatment groups per month. The overall effect will be this parameter estimate x 5. We anticipate using an unstructured covariance matrix for deriving the error term.

Our sample size estimate was based on the minimal clinically important difference in change in outcomes from 0 to 5 months. We have expressed this effect size as a moderate (d = .50, that is one half a standard deviation) difference in reduction on CBCL externalizing score for treatment group compared to control. Setting our Type I error rate (alpha) at 0.05. Thus, we require 85 participants in each group, for a power of 0.90, and a total sample size of 170 (we will recruit 200 to account for losses). This effect is reasonable to expect given the larger effects seen in children with ODD and ADHD in our previous studies (9). The target sample size is attainable based on the strong relationships we have with FASD diagnostic clinics and FASD Support groups across Canada.

A sub-study will be conducted as part of this trial which is described next.

**Feasibility Sub-Study (Optional Interview)**

**Rationale**

Feasibility of the Strongest Families FASD Program (i.e. user satisfaction, perception of burden, perceived utility) and levels of compliance will be examined as a sub-study. This study is exploratory in nature; consequently no hypotheses have been formulated. Evidence of program feasibility can be used to support changes in policy by key decision-makers and provide the basis for developing promising practices in the area of interventions for families affected by FASD.

**Methods**

**Participants**
Participants will be the first 12 individuals randomized to the intervention group, who have agreed during Consent to be contacted for an interview and we are able to reach and complete an interview.

Procedure

Participants who have Consented to the Feasibility Sub-Study and have been assigned to the intervention group will be contacted two months after randomization (approximately the middle of the intervention program). Participants will be contacted in the order in which they are randomized until we successfully reach 12 participants who agree to be interviewed. Participants who ask to be withdrawn from the trial prior to two months post-randomization will still be offered to participate in this interview and complete the CSQ-8 prior to withdrawal (at the time of their withdrawal request).

A 30-minute individual telephone interview will be performed over the phone asking participants about their experience with the program (e.g. what they like, what they do not like, what they find difficult, why they dropped out (if applicable), etc.). The Client Satisfaction Questionnaire (CSQ-8), a standardized tool to evaluate their satisfaction with the intervention, will also be administered over the phone after the interview. The telephone call will be audio recorded and transcribed for data analysis.

Participants will be compensated for their time with a $20 gift card (e.g. Loblaws, Wal-Mart or iTunes).

Measures

The Client Satisfactions Questionnaire (CSQ-8) (Appendix B-6): as described above (p. 5).

Feasibility Interview This semi-structured interview was developed in-house by an Undergraduate student, under the supervision of Dr. Anna Huguet, Research Associate for Dr. Patrick McGrath, PI. The measure consists of open-ended questions and ratings of specific program features. The attached interview (Appendix B-8) is a guide; the exact questions may vary slightly without changing the purpose of the interview.

Web Analytics Data (i.e. measurement of website activity such as pages visited, number of visits, time spent on sessions, etc.) is automatically tracked by IRIS.

Data Analysis

The qualitative data from the semi-structured interviews will be transcribed and transcripts will be coded and analyzed. Inductive thematic analysis of this qualitative data will be performed (18).

The quantitative data collected during the interview through close-ended questions and the CSQ will be summarized using descriptive statistics (frequencies for categorical variables, and medians and ranges for continuous variables). We will use the SPSS version 20 to perform these quantitative analyses.
Potential Benefits to Subjects and Others

We anticipate that parent participants, who receive the Strongest Families FASD program, will experience a positive change in the behaviour of their child with FASD, as well as positive changes to the family as a whole. Improvements in child behaviour can help build strong relationships between the parent and child, often leading to decreased parental stress. The strategies and coping mechanisms that are taught throughout the program will ideally be adopted to make life-long, sustainable changes. Participants may also find it satisfying to contribute to FASD research programs and extend their knowledge of FASD. In addition, participants will receive a $25 gift card at each of the 3 assessment times and, for those who complete the Optional Feasibility Interview, an additional $20 gift card.

Potential Harm to Subjects and Others

While it is very unlikely that any harm associated with this study will result, it is possible that some participants may have negative feelings when they respond to sensitive questions on the CBCL or the DASS. Participants can opt out of any questions that make them uncomfortable. Participants may also withdraw from the study at any point. There is a small burden of time and focus associated with completion of the assessment questions and the interview.

Alternative Treatments or Procedures

The standard of care for families affected by FASD is varied and can depend on the types of resources available and the capacity to provide services. Standard of care can include referrals to specialist healthcare providers (i.e., speech language pathologists, occupational therapists, physiotherapists), counselling services (i.e., mental health resources and behavioural therapists), and education (i.e., information about community services and programs). The Strongest Families FASD program is being offered in addition to and is intended to supplement, not replace the standard of care. Both the Intervention and Control Groups may receive any additional services offered or available to them during the trial (there are no restrictions on the care that they can receive).

Minimizing Potential Harm

Confidentiality

All information gathered during the course of this study is private and confidential. Only designated members of the research team will have access to participant data files. All CRFH research staff and Strongest Families staff are trained to maintain participant confidentiality and have signed confidentiality agreements.
Paper Records

IWK Site

All paper study documents will be stored in a restricted, secure area within the Centre for Research and Family Health at the IWK Health Centre.

Strongest Families Institute Site

As the Strongest Families Program is completed online, there will typically be no paper files generated during program completion. However, to prepare for the event of a temporary internet or power failure, Strongest Families will maintain participant contact information in paper format. Coaching sessions may also be completed on paper at times when the internet is unavailable and will be stored in participant files at SFI as source documentation for study activities. Data collected on paper will be entered into the IRIS system at a later date and documented as a “late entry”. Any paper records pertaining to study participants who complete the Strongest Families Program will be stored in a locked area at Strongest Families Institute for 5 years post-publication, at which time they will be destroyed as per IWK Research Ethics current recommendations.

Recorded Calls

Coaching telephone calls for the intervention group will be recorded at Strongest Families Institute and satellite offices and are saved directly to a local server housed at SFI in a restricted access area. Off-site coaches employ a hard wire connection to individual routers configured to meet SFI security standards and Virtual Private Network connected to the SFI local server using Cisco software, the industry leader for corporate networks. Calls may be transferred to Managers for Quality Assurance and training purposes using E-courier, an encrypted, password protected file and message delivery service (https://e-courier.ca/). Calls are retained for a maximum period of 6 months for Quality Assurance and are then deleted.

Calls for the optional Feasibility Interview will be recorded at the Centre for Research in Family Health using Algo Enterprise Call Recording (ECR) Software. Calls are stored on a local server in a locked area. User accounts are created by an administrator who controls security privilege options (e.g. restrict call access by other users). Calls will be deleted after transcriptions have been verified by study staff.

Electronic Records (IRIS)

Study staff and participants will be issued a unique username and password to log in to IRIS. Participant usernames are auto generated and private and passwords are salted/encrypted.
All electronic data will be stored on a secure server operated by Dynamic Hosting who subcontracts space from IAI. IAI is an industry leader in secure data hosting and transfer for government and institutional IT operations. IAI is currently undergoing the SOC 2 audit process and will be proceeding with CSAE-3416 audit in May 2014 (expected to be completed in January 2015). Perimeter security to the building is secured by a card access system. There are no public zones. All IAI staff are security cleared and cleared by criminal background checks. IAI’s data centre has Dual A/B power systems, that have full inline UPS and Diesel generator back up to assure uptime is near 100%. The IAI facility has a full 2N distribution path allowing for maximum uptime and reliability.

Data centers are located in Halifax, with all data stored in Canada at all times.

Additional information is available from the following web addresses: https://www.dynamichosting.biz/ and http://www.internetworking-atlantic.com/.

Data entered into IRIS will be archived after study results are published (i.e. they will not be visible or accessible to system users). All identifying information will be deleted by a programmer from the archived database five years post-publication (i.e. personal identifying information such as name and contact information, will be permanently removed from IRIS).

**Email Correspondence**

As most of the study is conducted online, correspondence with study participants will occur primarily via email. To enhance security, email containing sensitive information (e.g. Assessment Results, Mid/End Treatment Letters) will be sent only to the participants’ email account within the IRIS website. General notifications (e.g. “You have mail waiting in IRIS”) or assessment reminders will be sent to personal email accounts outside of IRIS. NOTE: Any communications with participants may also be sent via post, as circumstances dictate (e.g. difficulty contacting via email and/or via telephone).

**Data Sets**

Participant names will be replaced with ID codes in de-identified datasets. Only de-identified data (e.g., datasets with participant names and contact information removed) will be transferred to statisticians and/or collaborating teams, as required for research purposes. All study records will be stored for a period of five years past the date of publication. Published reports will only refer to demographics for the sample and analysed data based on group (Intervention and Control). In the case of an audit, study records may be shown to the IWK Health Centre Research Audit Committee.

All participant records will be retained for a period of 5 years post-publication at which time they will be destroyed according to current research practice recommended by IWK Research Services.
Monitoring for Safety During SF-FASD Program (Strongest Families Institute)

Child Protection

SFI staff are highly trained and have written procedures in place to ensure appropriate action, reporting, and documentation in situations regarding the safety of any individual or suspected abuse and/or neglect of a child. Further, in accordance with provincial laws, in the rare event that staff suspect or are aware of a situation where a child is being harmed, they would report this to the respective child protection agency.

Adverse Events

Based on our experience with similar research protocols, we do not expect that a Serious Adverse Event or Adverse Event will occur as a result of taking part in this low risk study.

At the beginning of each telephone session, the coach routinely reviews with the parent/caregiver how the skills have been working and how the child’s behaviour has been since the previous session. Any report of a serious event (i.e. death, a life-threatening experience, inpatient hospitalization/ prolongation of hospital stay, lasting disability or a visit to an Emergency Room for mental health care) for the parent or child will be documented in study records as an Adverse Event.

In order that we collect necessary information while maintaining privacy, the coach/study staff who receives the initial report will document the type of event reported and ask the participant the question below:

**Event Reported:**

- ☐ Visit to Emergency room - mental health care
- ☐ Visit to Emergency room - NOT mental health care
- ☐ Event resulting in lasting disability
- ☐ Event resulting in hospitalization/prolongation of hospital stay
- ☐ Life-threatening event ☐ Death
- ☐ Other

Q: “Would you say this event was…”

- ☐ definitely related to taking part in this study
- ☐ maybe related to taking part in this study
- ☐ definitely NOT related to taking part in this study
- ☐ unsure

A response of “definitely NOT” will be documented and no further questions will be asked.
A response of “definitely”, “maybe” or “unsure” will prompt the coach to collect the following information:

Details of the Incident:
What occurred? (Child or caregiver)
When did it occur? (start date-end date)
What actions were taken to resolve the issue (e.g. treatment)?
Is there any follow up required?

Events will be reviewed by the PI (in consultation with the REB, as necessary) for relatedness to study participation. Any of these events deemed by the PI to be related or possibly related to study participation will be reported to the REB as a Adverse Event. The Co-Investigator (or delegate) at Queen’s University will be notified and will be responsible for informing the Queen’s University ethics committee, as per their requirements. Appendix E-3 shows the electronic information collection form which is accessible to staff within IRIS.

Monitoring for Safety During Study Activities (IWK/Queen’s)

Child Behaviour Checklist (CBCL)

Risk Items Endorsed in IRIS (Automated Messages)

Endorsement of specific items on the CBCL indicative of a potential risk to safety will trigger automatic responses from IRIS, depending on the items endorsed (see table below).

<table>
<thead>
<tr>
<th>Questionnaire Item</th>
<th>CBCL 1 ½ - 5</th>
<th>CBCL 6-18</th>
<th>Min. Score Required to Trigger Message</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unhappy, sad or depressed</td>
<td>✔</td>
<td>✔</td>
<td>2</td>
</tr>
<tr>
<td>Talks about killing self</td>
<td>✔</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Deliberately harms self or attempts suicide *triggers follow up questions</td>
<td>✔</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Hears sound or voices that aren’t there (describe)</td>
<td>✔</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Sees things that aren’t there (describe)</td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Runs away from home</td>
<td>✔</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Uses drugs for nonmedical purposes</td>
<td>✔</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Physically attacks people</td>
<td>✔</td>
<td>✔</td>
<td>1</td>
</tr>
<tr>
<td>Sets fires</td>
<td>✔</td>
<td></td>
<td>1</td>
</tr>
</tbody>
</table>

Endorsement of the item “Deliberately harms self or attempts suicide” will automatically trigger the following questions:
1) Which behaviour is true for your child

☐ deliberately harms self
☐ attempts suicide

If YES to “attempts suicide”:

a. Has your child attempted suicide in the last 6 months? ☐ Yes ☐ No

b. Is your child still at risk of attempting suicide
   (that is, do you think this may happen again?) ☐ Yes ☐ No

i. IF YES to b “still at risk”: Is your child under care of a health care professional who is aware of this risk? ☐ Yes ☐ No

Suicide attempts within the previous six months or a current risk of suicide will be an exclusion from the study. As the SF-FASD program is intended to help mild to moderate behaviour problems, it is the opinion of the PIs that the complex nature of an active suicide risk should preclude study participation.

If the child is currently at risk and is not being monitored by a health care professional, an automatic message will appear, as follows:

“We highly recommend that you seek help from a professional health care provider, such as your child’s doctor. If you feel that your child is an immediate danger to him/herself please go to your nearest Emergency Room or call 911.”

Endorsement of an unmonitored current suicide risk will be followed up with a phone call from the Study Coordinator (or delegate) to ensure that the participant has received and understood the recommendation for follow up.

Endorsement of “deliberately harms self” or any of the remaining items listed in the table above will be automatically populated into a summary of the endorsed items and a safety recommendation to be shown to the participant at the time the online questionnaire is completed (when the SUBMIT button is clicked in IRIS). Participants may choose to send a copy of this message to their inbox within IRIS for their own records.

“You answered that your child:

[Item 1]
[Item 2]
[Item 3]...etc

“Depending on the situation, this may be concerning. If you are worried about this behaviour and are not already receiving professional help we encourage you to talk to your child’s doctor or other health care professional.
If you feel that your child may be in immediate danger of seriously harming him/herself or someone else, you should seek help right away by going to your nearest emergency room or calling 911.”

Risk Evident from Computed Scores (Assessment Results Letter)

In cases where participants score within the Clinical Range for Internalizing, this information will be provided in the Assessment Results (Appendices D-3, D4, and D-8 to D-10) with the recommendation to follow up with a health care professional (if the parent has not already done so). Elevated Internalizing scores are not unexpected, therefore we will follow up by telephone only for those whose child’s score increases from normal or borderline to clinical at 5 and 11 month follow up assessments. The follow up telephone call is to ensure that the participant has received and understood the recommendation.

Depression Anxiety Stress Scale-21 (DASS)

Item Endorsed in IRIS (Automated Message)

Endorsement of the item “I felt that life was meaningless” will trigger the following automated safety recommendation to be shown to the participant at the time the online questionnaire is completed (when SUBMIT is clicked in IRIS):

“You answered that you felt life was meaningless [some of the time/a good part of the time/most of the time] in the last seven days.

If you are worried about this feeling, we encourage you to talk to your doctor or other health care professional.

If you ever feel that you are in immediate danger or harming yourself or someone else, you should seek help right away by going to your nearest emergency room or calling 911.”

Computed Scores (Assessment Results Letter)

Participants will receive feedback on each of the DASS-21 subscale scores by comparison of their scores to the general population (see table below). Participants who score Severe-Extremely Severe on any of the subscales will also receive a courtesy phone call from study staff (Study Coordinator or delegate) to ensure that recommendations have been received and understood.

<table>
<thead>
<tr>
<th>Severity Rating</th>
<th>Message</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal - Mild</td>
<td>Your feelings of [subscale] at the time you answered the questionnaire were about the same as most people.</td>
</tr>
<tr>
<td>Moderate</td>
<td>Your feelings of [subscale] at the time you answered the questionnaire were higher than most people.</td>
</tr>
</tbody>
</table>

Version: 15Dec14
Severe – Extremely Severe | Your feelings of [subscale] at the time you answered the questionnaire were much higher than most people.

All participants will receive the following recommendation in the Assessment Results Letters, regardless of their DASS scores:

“This is not a diagnosis. Your feelings of stress, anxiety or depression can change depending on what is happening in your life at the time you answered these questions. Everyone experiences feelings like these at different degrees. However, if you are experiencing these feelings often and strongly, you should talk to your doctor.”

**Study Personnel**

**IWK**

All IWK study personnel (with the exception of Megan Ross) have been involved in previous research studies and have CVs on file. CV for Megan Ross is attached to the Research Team Contact Page.

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Patrick McGrath</td>
<td>Co Principal Investigator</td>
</tr>
<tr>
<td>Dr. Anna Huguet</td>
<td>Research Associate</td>
</tr>
<tr>
<td>Karen Turner</td>
<td>Project Coordinator</td>
</tr>
<tr>
<td>Jessica Roane</td>
<td>Research Assistant</td>
</tr>
<tr>
<td>Emily Faulkner</td>
<td>Research Assistant</td>
</tr>
<tr>
<td>Amos Hundert</td>
<td>Research Assistant</td>
</tr>
<tr>
<td>Megan Ross</td>
<td>Student</td>
</tr>
</tbody>
</table>

**Offsite**

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. James Reynolds</td>
<td>Co-Principal Investigator: Dr. Reynolds will oversee all components of the Intervention program and the recruitment procedure. He will assist with study design, statistical analysis, and data interpretation and provide substantial intellectual contribution to all publications of the research findings (conference posters, presentations and peer-reviewed publications).</td>
</tr>
<tr>
<td>Dr. Amy Hewitt</td>
<td>Dr. Hewitt will provide support with study design and intervention content development. She will provide input for obtaining ethical approval from the IWK and Queen’s University REB. Dr. Hewitt will act as the Content Manager for the ‘Ask an Expert’ function.</td>
</tr>
<tr>
<td>Sue Kobus</td>
<td>Recruitment Coordinator: Ms. Kobus will provide administrative support for the activities at Queen's University, play a major role in recruitment, and support study staff when needed.</td>
</tr>
<tr>
<td>Angelina Paolozza</td>
<td>Ms. Paolozza will assist with recruitment and support study staff when needed.</td>
</tr>
</tbody>
</table>
In addition to leading the Recruitment Phase, the collaborators from Queen’s University will closely monitor the RCT progress.

<table>
<thead>
<tr>
<th>Co-Investigators</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name</strong></td>
</tr>
<tr>
<td>Ms. Heather Caughey</td>
</tr>
<tr>
<td>Dr. Chris Mushquash</td>
</tr>
<tr>
<td>Dr. Nazeem Muhajarine</td>
</tr>
<tr>
<td>Dr. Andre Sourander</td>
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<tr>
<th>Strongest Families Institute</th>
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</thead>
<tbody>
<tr>
<td><strong>Name</strong></td>
</tr>
<tr>
<td>Dr. Patricia Lingley-Pottie</td>
</tr>
<tr>
<td>April Schwanz</td>
</tr>
<tr>
<td>Michael Cameron</td>
</tr>
<tr>
<td>Kati LaVigne</td>
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<tr>
<td>Dale Knowles</td>
</tr>
<tr>
<td>Tanya McCoy</td>
</tr>
<tr>
<td>Natalie Rourke</td>
</tr>
<tr>
<td>Misha Leach</td>
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<tr>
<td>Conor Murphy</td>
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</tbody>
</table>

The Coach Supervisor and Coaches listed above are all highly experienced Strongest Families Institute staff and have demonstrated competency in the Strongest Families behavioural program.
References


Appendices

Recruitment and Consent Materials

(A-1) Recruitment Brochure
(A-2) Recruitment Email
(A-3) Recruitment Poster
(A-3.1) Sample Recruitment Web Ad
(A-4) Recruitment Telephone Script
(A-5) MyStudies Screen Shot Sample
(A-6) MyStudies Landing Page – FASD Study Text
(A-7) Screening for Eligibility
(A-8) Participant Consent Form
(A-9) Authorization Consent Form
(A-10) Sample Social Media Posts
(A-11) Recruitment Survey

Measures

(B-1) Demographics- Baseline
(B-2) Demographics – Follow up (5 & 11 month Assessments)
(B-3) Child Behavior Checklist 1½-5 (CBCL)
(B-4) Child Behavior Checklist 6-18 (CBCL)
(B-5) Depression Anxiety & Stress Scales Short Form (DASS-21)
(B-6) Client Satisfaction Questionnaire – 8 (CSQ-8)
(B-7) Strongest Families Program Satisfaction Questionnaire
(B-8) Feasibility Interview Guide (Optional Sub-Study)

Program Materials

(C-1) Strongest Families FASD Session Summaries
(C-2) Reward Chart
(C-3) Daily Strengths Chart
(C-4) Visual Schedule Template
(C-5) Tryout Pages
(C-6) Ask an Expert Message Board (Screenshot)
(C-7) Control Group Static Resource Webpage (Screenshot)
(C-8) Blank Visual Schedule Template
(C-9) Tips for Teachers

Participant Correspondence

(D-1) Baseline Withdrawal (Exclusion)
(D-2) Baseline Withdrawal (Exclusion) Telephone Script
(D-3) Group Placement - Intervention
(D-4) Group Placement - Control
(D-5) Mid-Intervention Progress - Intervention
(D-6) Mid-Study Progress - Control
(D-7) End Intervention Progress
(D-8) 5 Month Assessment Results
(D-9) Study Completion - Intervention
(D-10) Study Completion - Control
(D-11) Re-contact - Intervention
(D-12) Re-contact - Control
(D-13) Re-contact Reminder Email (Intervention)

Other

(E-1) CV Dr. Hanlon-Dearman
(E-2) CV Dr. Christine Looke