

RESEARCH ARTICLE

A Study Protocol for the “Practitioner Training in Child and Adolescent Psychiatry” Cluster-randomized Pilot Study

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Abstract

Background: Primary care providers (PCPs) are increasingly called upon to assist in meeting the growing demand for paediatric mental health care in Canada, yet they report inadequate training and confidence to do so. The Practitioner Training in Child and Adolescent Psychiatry (PTCAP) program was designed to fill this gap by teaching PCPs the skills needed to provide frontline care themselves, particularly in rural/remote regions where specialist resources are limited. This innovative educational intervention may improve paediatric mental health care capacity, but a pilot study is needed. **Methods:** We designed a cluster randomized, controlled pilot of PTCAP. Random assignment to intervention or control (treatment-as-usual) will occur at the practice level. Participating PCPs (N=61) at sites randomized to intervention will receive eight hours of training in the use of practice guidelines and brief counseling techniques (i.e., common skills/elements) for addressing diagnosable conditions and more general, transdiagnostic concerns. Mental health care capacity at one-week post-intervention will be the primary outcome, assessed through self-report questionnaires of mental health care confidence, and through a more objective, observational assessment of trained skills. We will also examine retention of these skills at one-month follow-up. We expect use of trained common skills/elements to be associated with better child mental health outcomes on the Strengths and Difficulties Questionnaire (N = 250). **Discussion:** As one of the first RCTs of its kind in Canada, this study will provide unique, preliminary evidence in regards to the feasibility and efficacy of the PTCAP intervention for enhancing rural, paediatric mental health care capacity.

Key Words: primary care provider; rural, medical education; child and youth; mental health; common factors

Résumé

Contexte: Les prestataires de soins de première ligne (PSPL) sont de plus en plus sollicités pour aider à répondre à la demande croissante de soins de santé mentale pédiatriques au Canada, et pourtant, ils déplorent une formation et une confiance inadéquates pour ce faire. Le programme de Formation du médecin en psychiatrie de l'enfant et de l'adolescent (FMPEA) a été conçu pour combler cette lacune en enseignant aux PSPL les aptitudes nécessaires pour prodiguer eux-mêmes les soins de première ligne, particulièrement en région rurale/éloignée où les ressources de spécialistes sont limitées. Cette intervention éducative innovatrice peut améliorer la capacité des soins de santé mentale pédiatriques, mais une étude pilote est requise. Méthodes: Nous avons conçu un pilote contrôlé en grappes randomisées de la FMPEA. Cette assignation aléatoire de l'intervention ou du contrôle (traitement habituel) aura lieu au niveau de la pratique. Les PSPL

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participants (N = 61) aux endroits aléatoires de l'intervention recevront huit heures de formation en matière d'utilisation des lignes directrices de la pratique et de brèves techniques de consultation (c.-à-d., aptitudes/éléments communs) pour aborder les affections qui peuvent être diagnostiquées et des problèmes trans-diagnostiques plus généraux. À une semaine après l'intervention, la capacité des soins de santé mentale sera le principal résultat, évalué par des questionnaires auto-déclarés sur la confiance dans les soins de santé mentale, et par une évaluation observationnelle plus objective des aptitudes apprises. Nous examinerons également la rétention de ces aptitudes au suivi d'un mois. Nous prévoyons que l'utilisation des aptitudes/éléments communs appris soit associée à de meilleurs résultats de santé mentale des enfants au questionnaire des forces et des difficultés (N = 250). Discussion: À titre d'un des premiers essais randomisés contrôlés (ERC) du genre au Canada, cette étude offrira des données probantes préliminaires uniques à l'égard de la faisabilité et de l'efficacité de l'intervention de FMPEA pour améliorer la capacité des soins de santé mentale pédiatriques en milieu rural.

Mots clés: prestataire de soins de première ligne, rural, formation médicale, santé mentale des enfants et des adolescents, facteurs communs

Background

An estimated one million Canadian children experience a clinically significant mental health concern in a given year (Mental Health Commission of Canada, 2013). Unfortunately, the majority do not receive the necessary treatment (Waddell, Shepherd, Schwartz, & Barican, 2014). Community stigma, financial burden and time costs associated with accessing specialist services help to explain this care gap, particularly in rural and remote regions where local resources are limited. The primary care context offers a solution that is affordable, accessible and relatively free of the stigma associated with specialized treatment facilities (Oandasan, Malik, Waters, & Lambert-Lanning, 2004; Windrim, 2003). But, while it is proposed that common child and youth mental health concerns can be effectively identified and managed within the primary care setting (Kutcher, 2010; Steele et al., 2012; World Health Organization, 2015), this aspiration has not yet been realized. Rural primary care providers (PCPs) report inadequate training and confidence to provide this care and they express a clear need and desire to participate in available educational opportunities (Steele et al., 2012; World Health Organization, 2015; Zayed et al., 2016). To meet this need, we developed the Practitioner Training in Child and Adolescent Psychiatry (PTCAP) program. We based the program on a national needs assessment with rural PCPs (Steele et al., 2012), which revealed a preference for skills training (rather than just guidelines) by PCP-psychiatrist pairs, in the community. An innovative knowledge translation framework also informed the course content, delineating the kinds of skills PCPs need to effectively and confidently deliver mental health care (Brown & Wissow, 2012).

Most previous educational efforts have emphasized evidence-based practice guidelines and intervention protocols for titrating care and providing brief therapy for diagnosable disorders (Asarnow, Rozenman, Wiblin, & Zeltzer, 2015; Kolko & Perrin, 2014). This approach demonstrates clear efficacy in managing targeted conditions in primary care, particularly major depression in adults (Kolko &

Perrin, 2014). However, a focus on diagnosable disorders alone can have the unintended effect of leaving untreated the majority of children and youth in primary care with comorbid and sub-threshold, yet distressing symptoms. Also, the complexity and sheer number of guidelines and protocols needed to address every specific condition and population requires either extensive, ongoing training for PCPs or a reliance on mental health specialists that is not feasible in some rural and underserved settings.

The PTCAP program addresses these limitations by taking a combined approach; merging the standard, diagnosis-specific focus on practice guidelines, with a novel, transdiagnostic focus on common factors skills (Brown & Wissow, 2012). PTCAP emphasizes practical skills PCPs can use themselves within the time constraints of a medical visit to address mild to moderate concerns. This approach emphasizes aspects of the therapeutic encounter that account for a large portion of the variance (between 30% and 70%; Imel & Wampold, 2008) in patient outcomes, irrespective of the diagnosis or treatment, which are therefore valuable pathways for interventions to improve paediatric mental health functioning in primary care.

These “common factors” fall into two broad categories: 1) therapeutic relationship (e.g., client engagement and therapeutic alliance); and, 2) client characteristics (e.g., motivation to change and hopefulness regarding treatment). PCPs can be taught to use brief interviewing and counseling techniques, or “common skills”, derived from motivational and family interviewing, to bring about improvements in these factors and to enhance outcomes (Brown & Wissow, 2012; Asarnow et al., 2015; Kolko & Perrin, 2014; Imel & Wampold, 2008; Wissow et al., 2008). In addition, PCPs can be trained to use brief, therapeutic techniques, or “common elements”, to build relationships with families by immediately addressing their concerns and providing hope and relief. Common elements are techniques shared across a number of evidence-based interventions for a specific disorder that PCPs can apply broadly to symptom clusters (i.e., anxious or depressive feelings; attention and behavioral issues)

when a particular diagnosis does not apply, families are not receptive to a diagnosis-driven approach, and/or specialist services are unavailable (Brown & Wissow, 2012; Wissow et al., 2008; Wissow et al., 2015). The use of common factors skills by clinicians in primary care has been associated with enhanced patient-centered care. Patient-centered care refers to a collaborative approach to medical care in which practitioners work with patients to define their main concern and to establish a plan of care. In turn, the provision of more patient-centered care was associated with better child and youth mental health functioning (Wissow et al., 2011).

This study will represent the first pilot of the PTCAP program. We hypothesize that PTCAP's combined approach to knowledge translation will be associated with improvements in PCP mental health care capacity, including use of trained skills and confidence in these skills for addressing general mental health concerns themselves using practice guidelines and common skills/elements. In addition, we hypothesize that increased use of common skills/elements will be associated with enhanced patient-centeredness that, in turn, will be associated with improved child/youth mental health functioning. Finally, we expect that the qualitative data will indicate feasibility of the program.

Methods

Aims

The aim of this cluster-randomized pilot is to assess trial feasibility and to determine whether the PTCAP intervention enhances PCP mental health care capacity, which will be operationalized as observed use of trained skills and self-reported confidence in these skills. The aim is also to assess whether increased use of common skills/elements translates into improved child/youth mental well-being.

Design

This study is a cluster-randomized trial conducted at the University of Western Ontario (ISRCTN trial registration number: ISRCTN65931294). Quantitative data will address both intervention efficacy and potential mediators/moderators of any effects, while qualitative data will speak to the acceptability and feasibility of the intervention and trial to inform future program improvements and scale-up. The protocol for this study was informed by a previous study of common skills training carried out with clinicians in primary care (Wissow et al., 2008; 2011).

Settings and Participants

A multi-site study will be conducted with family practices located in rural Southwestern Ontario. Participants will include PCPs working at these practice sites.

In addition, participants will include families with at least one child between the ages of 6 and 18 attending a medical visit at a participating practice following delivery of the

PTCAP intervention. Inclusion criteria will be as follows: 1) PCPs (i.e., family physicians, family medicine residents, nurse practitioners, and paediatricians); 2) practicing at a family practice located in a rural region (population under 100,000, where 0 to 30% of the population commutes to work in a large urban center; Pong & Pitblado, 2005) of Southwestern Ontario.

There are no exclusion criteria. While participation in the educational sessions will be open to all staff, only PCPs will participate in the evaluation.

Recruitment

Based on information provided on the Ministry of Health and Long-term Care website, we will compile a list of contact information for the executive directors and team leads of all family health teams located in rural Southwestern Ontario. We will first attempt to contact these team directors and leads via email using a generic email advertisement. A modified Dillman approach (Dillman, 2011) will be employed to enhance response rates such that a second email will be sent if there is no response to our first email after two weeks. If there is no response to the second email attempt at contact, site directors and/or leads will be contacted directly, over the phone. A fourth and final contact attempt will be made by phone if there is no response to our third attempt at contact. Directors or team leads will be asked to provide verbal consent to have their family practice team participate in the study. Individual PCPs working at these family practices will be asked to provide individual written consent to participate, prior to completing baseline measures. PCPs not interested in participating in the study can still participate in the intervention but will not be asked to complete any measures.

Following delivery of the PTCAP intervention, families attending a medical visit at a participating family practice will be recruited to participate in the study by office staff and an advertisement posted in the waiting room. Office staff will provide a package of self-report questionnaires to families who wish to participate in the study.

Randomization

Randomization of PCPs to intervention or control will occur at the family practice (i.e., cluster) level, stratified by geographical region of Southwestern Ontario. Intervention and control sites will be matched based on the number of participating PCPs (i.e., cluster size) (see Figure 1). A researcher blind to site identity (SE) will conduct the randomization process using a web-based random number generator (Random.org). SG will allocate practices using a 1:1 ratio within strata (i.e. regional location of Southwestern Ontario: north, east, south, and west).

Intervention. The PTCAP educational intervention will be delivered to participants from family practices randomized

to the intervention arm of the study. PCPs will receive 8 hours of didactic and case-based skills training in the combined use of practice guidelines for managing, referring, and obtaining consults regarding specific, diagnosable conditions, and brief, broad-based counseling and therapeutic techniques for addressing more general, sub-threshold concerns. In order to maximize attendance, the intervention will be flexibly delivered (e.g., one, two or more sessions) and scheduled according to each site's preference and availability. Sessions will be video-recorded for fidelity purposes and to support future improvements in program design and content.

PCPs will receive three educational modules delivered in the following order: 1) Common Skills (i.e., communication and counseling skills for eliciting mental health concerns and managing mental health conversation with families (Wissow et al., 2008); 2) Practice Guidelines (i.e., tools to support assessment, diagnosis, information sharing, and referral/consultation for ADHD, behavioral disorders, anxiety, depression and suicidality); and 3) Common elements (i.e., brief, broad-based therapeutic techniques for addressing symptom clusters related to attention and behavioral issues, and anxiety and depressive symptoms) (see Figure 2). Intervention materials are available upon request at www.PTCAP.ca.

Program delivery will consist of didactic teaching and case-based discussion. In addition, PCPs will be shown twelve short (two minutes on average) videos and three longer videos (15 minutes on average) demonstrating implementation of the common skills and common elements, respectively, within a medical visit. In keeping with the preferred mode of educational delivery expressed by rural PCPs across Canada (Steele et al., 2012), mental health training will be delivered on site by one of three child and adolescent psychiatrist/family physician pairs. This pairing will ensure that PCPs receive a balanced perspective that combines the clinical expertise of the child and adolescent psychiatrist with the practical perspective of the busy PCP who must deliver mental health support within the time constraints of a medical visit.

Psychiatrist/physician pairs will remain independent of the evaluation.

PCPs will not be compensated for their time participating in the intervention as this might reduce their inherent motivation to provide mental health care (Dec, Koestner, & Ryan, 1999), producing an estimate of effect which is not generalizable to the larger population in whom reimbursement for this kind of care is unlikely to be part of policy. However, family physicians will receive Mainpro M1 continuing medical education credit for participating in the intervention.

Control. Family practices assigned to the control will be encouraged to deliver treatment as usual (TAU). Based on

a focus group we conducted with rural PCPs practicing in rural Southwestern Ontario, TAU consists of referrals to in-house social workers/other mental health specialists where available, or to urban centers for specialized care (Gotovac, Espinet, Lingard, & Steele, paper in preparation). The PTCAP program will be offered to control sites following completion of the evaluation, ensuring equal access to any enhancements in care after the intervention for all patients.

Data Collection and Outcome Measures

Demographic data will be collected from PCPs and patients as part of a package of questionnaires, including information on age, gender, as well as degree, specialty, and length of time in practice for PCPs. At the PCP level, the primary outcome of interest will be PCP mental health care capacity measured at one-week post-intervention to examine the immediate effect of training. Capacity will be operationalized as the use of trained mental health skills and self-reported confidence in these skills. Skills include the use of practice guidelines and common skills/elements for addressing diagnosable conditions and more general concerns (or while waiting on diagnosis/referral).

At the patient level, the primary outcome will be child mental health functioning at four-month follow-up, which will afford the time needed for patients to follow-up with their PCPs after their medical visit and for any intervention effects on PCP practice to impact actual patient care. Secondary outcomes of interest for PCPs will be mental health care attitudes and knowledge at one-week post-intervention, and use of trained skills and patient-centeredness at one-month follow-up to assess for retention of enhanced mental health care capacity over a longer-term. Secondary outcomes for patients will be parent/youth satisfaction with the medical visit immediately following their appointment and parent mental health functioning at four-month follow-up.

Primary Outcome Measures for PCPs. Wissow and colleagues have demonstrated that patient-centeredness, particularly in combination with use of trained common skills, is associated with improvements in child and youth mental health functioning (Wissow et al., 2011). As such, these videos will also be coded for PCP patient-centeredness using the widely used and well-validated, Roter Interactional Analysis System (RIAS; Roter & Larson, 2002), which is used to code practitioner and patient communication during medical encounters.

PCP and patient utterances will be coded into exclusive communication categories, and patient-centeredness will be scored as a ratio between patient-centered categories of talk (psychosocial or lifestyle-related issues, physicians' information giving about biomedical topics, all patients' questions, all physicians' emotionally focused talk, and partnership talk) divided by practitioner-centered categories of talk (biomedical questions by PCP or patient, PCP directive statements, and patient biomedical information giving).

A ratio greater than one indicates a more patient-centered approach, while a ratio less than one, a more practitioner-focused manner.

Two researchers, blind to PCP allocation status and data collection time-point, will carry out the coding. Ten percent of the videos will be double-coded to check for reliability. Inter-rater reliability will be assessed intermittently throughout coding to guard against drift. A cut-off level of a Kappa coefficient of $<.6$ will be used to indicate low inter-rater reliability, which will prompt refresher training with coders, including collaborative coding of a practice video.

Four self-report measures will be used to assess PCP mental health care confidence:

1. Provider Confidence Scale (Pr-CS; Brown, Riley, & Wissow, 2007). The Pr-CS is an 11-item scale that assesses the degree of comfort practitioners feel managing *general* child and adolescent mental health concerns *themselves*, including emotional and behavioral problems, short attention spans, and trouble getting along with friends (children) / problems with conduct outside the home (adolescents). Each concern is rated on a scale of 1 to 5, with higher scores indicating greater comfort. The scale has previously been used to measure PCP confidence in communicating with children and their parents about mental health concerns and demonstrates good internal consistency ($\alpha = .90$) (Brown et al., 2007).
2. Physician Confidence Questionnaire (PCS; Garcia-Ortega et al., 2013). The 8-item PCS measures practitioner confidence in assessing, discussing, providing information and pharmacotherapy and referring child and adolescent mental health concerns, consistent with the use of *disorder-specific, practice guidelines*. The PCS has previously been used to examine PCP (including non-physicians) confidence in assessing and managing diagnosable conditions and demonstrates good internal consistency ($\alpha = .88$) (Garcia-Ortega et al., 2013).
3. Ease of Consultation Scale (ECS; Wissow et al., 2008). The 8-item ECS measures perceived level of difficulty in obtaining a consultation with other mental health professionals (e.g. social worker, clinical psychologist, etc.). The ECS has been used previously to assess PCPs' ability to consult with other mental health specialists in a medical setting (Brown et al., 2007).
4. Referral Comfort Scale (RCS; Brown et al., 2007). The Referral Comfort Scale

(RCS; Brown et al., 2007) is an 8-item tool that assesses PCPs' comfort (1 - not at all comfortable to 5 -extremely comfortable) determining when it is appropriate to refer a child or adolescent to other professionals who they perceive as better equipped to handle the presenting problem. Brown and colleagues have previously used this scale to measure PCP comfort with mental health referrals for school-aged children (Brown et al., 2007).

Given sufficient overlap amongst these measures based on factor analysis, a composite skill uptake score will be created by combining z-scores on these measures.

Primary Outcome Measure for Patients. Child mental health functioning will be measured using the well-validated and standardized Strengths and Difficulties Questionnaire (SDQ; parent and youth versions, Goodman, 1997). The SDQ is a 25-item child/youth behavioral screening tool that measures emotional difficulties, conduct problems, hyperactivity/inattention, peer relationship problems and pro-social behavior.

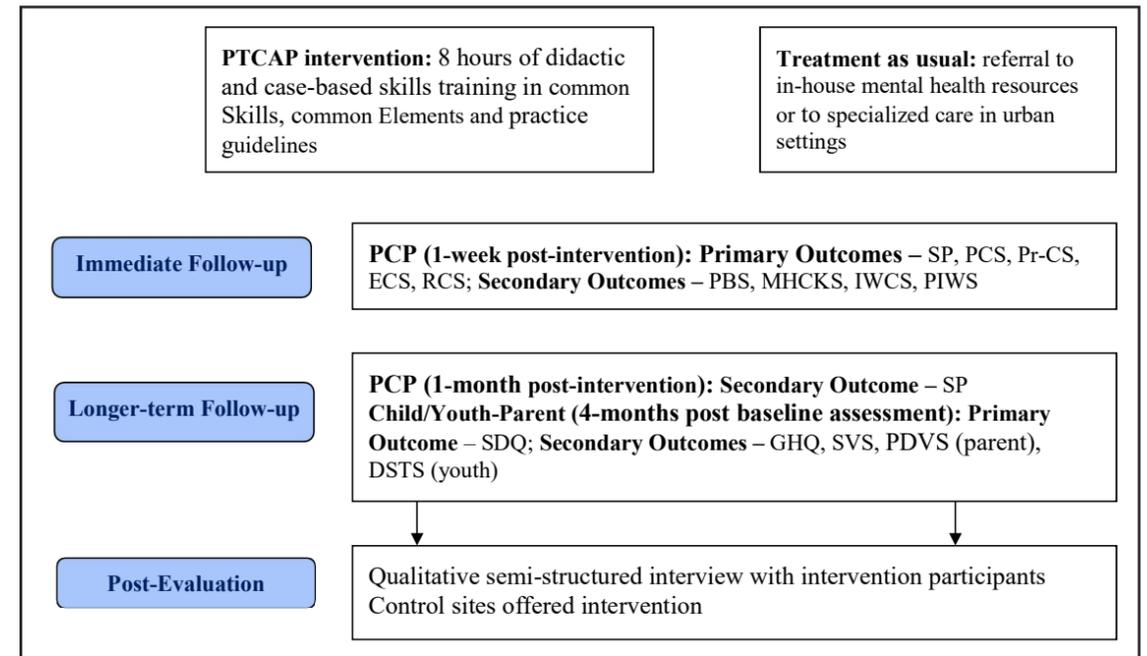
Secondary Outcome Measures for PCPs. The secondary outcomes of interest will be measured using the following two scales: (1) Physician Belief Scale (PBS; Ashworth, Williamson, & Montano, 1984). The PBS is a 14-item measure of physician's attitudes towards treating mental health problems in primary care, with lower scores indicating more positive attitudes (e.g., the provision of mental health care by PCPs is seen as feasible and useful). (2) Mental Health Care Knowledge Scale (MHCKS). The MHCKS is a 45-item true/false scale designed for this pilot study to measure mental health care knowledge related to common skills/elements and practice guidelines.

In addition, potential moderators of outcomes will be measured using two scales.

1. Influence of Workplace Characteristics Scale (IWCS). This is an 8-item scale designed to assess the influence of workplace characteristics, such as flexibility in patient scheduling, on PCP mental health practice (Wissow et al., 2008).
2. Perception of Influence Over Work Scale (PIWS) (Wissow et al., 2008). The PIWS is a 12-item scale that measures the practitioner's perception of their influence over their office environment, such as work hours and patient scheduling.

All of the questionnaires for PCPs and patients have been previously validated with the exception of the knowledge measure, which was created for this study as we were unable to find a suitable, previously validated measure. PCPs will complete all questionnaires at one week pre-intervention and at one-week post-intervention. The entire package of questionnaires for PCPs will require no more than 15 to 30 minutes to complete, per assessment. In addition, the

Figure 1. Randomization and measurement timeline.



NB. SP = Standardized Patient assessment; PCP = Physician Confidence Scale; Pr-CQ = Provider Confidence Scale; ECS = Ease of Consultation Scale; RCS = Referral Comfort Scale; GHQ = General Health Questionnaire; SDQ = Strength and Difficulties Questionnaire; PBS = Physician Belief Scale; MCKS = Mental Health Care Knowledge; IWCS = Influence of Workplace Characteristics on Mental Health Practice Scale; DSTS = Discussion of Sensitive Topics Scale; PDVS=Psychosocial Discussion During Visit Scale; SVS = Satisfaction with Visit Scale

standardized patient assessment will be re-administered at one-month follow-up. Family practices assigned to the control arm of the study will be matched with intervention sites based on geographical location and cluster size and will complete assessments according to the measurement schedule of the site they are matched with. All data will be collected onsite during prescheduled visits.

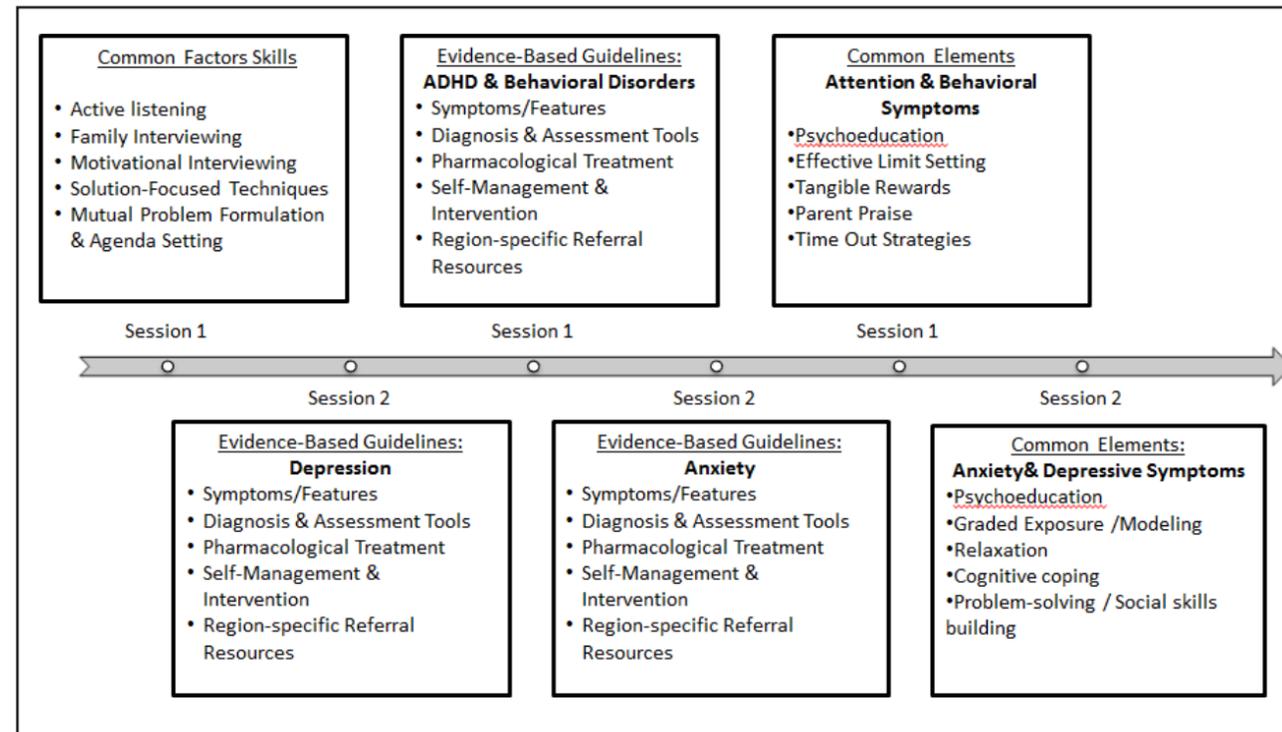
Secondary Outcome Measures for Parent/Youth Pairs. The following two measures will be used to assess secondary outcomes of interest:

1. Satisfaction with Visit Scale (SVS). This measure includes five items for parents / six items for youth (12 to 18 years) that assesses the degree to which the practitioner addressed and understood his/her concerns and involved him/her in their care (Wissow et al., 2008).
2. Psychosocial Discussion During Visit Scale (PDVS) for parents and the Discussion of Sensitive Topics Scale (DSTS) for youth (Wissow et al., 2008). The PDVS is a 5-item scale assessing the degree to which the parent feels that the PCP encouraged discussion about mental health concerns, while the DSTS is a 9-item scale that assesses whether or not various topics were discussed with the PCP during the visit (e.g., mood, getting into trouble for behavior).

Instructions included in the initial questionnaire package will direct parent-child pairs to complete one self-report measure prior to their medical visit (i.e., the SDQ) and three immediately following their medical visit (PDVS; SVS; and the DSTS). The order in which families complete their questionnaires will be confirmed at four-month follow-up.

Families with more than one child aged 6 to 18 years will be instructed in the questionnaire package to choose one child to participate for whom the study seems most relevant. Families with a child 12 years or older will be instructed to have their child complete the questionnaires for youth. Instructions provided in the questionnaire package will direct families to seal their completed questionnaires in the pre-stamped, self-addressed envelope provided and to either mail the package or leave it with front desk staff for pick-up by research staff. If parents sign the enclosed consent to participate in the follow-up assessment, research staff will contact parents by phone four months following completion of their baseline assessment. Questionnaire packages for families will require no more than 15 minutes to complete, per assessment. Parent-child pairs will be remunerated \$10 per package completed.

PCPs will be contacted within one week of completing the one-month follow-up to complete a semi-structured interview designed to elicit their perspective on specific aspects

Figure 2. PTCAP curriculum outline and implementation

of the program, including: the practice guidelines and common skills/elements for ADHD, depression, anxiety and behavioral disorders; region-specific resources; intervention resource binder; physician-psychiatrist pairing; intervention scheduling; and, intervention design and delivery (e.g., video discussion vs. didactic teaching). Participants will be asked which of these aspects they liked/didn't like or found useful/not useful and why, and in which ways the intervention should be modified for future implementations.

Blinding

SE will randomize the clusters and SG will allocate them, blind to site identity.

Researchers blinded to SP allocation status and time point, will code the videos (two independent student researchers) and analyze the data (SE).

Sample size

To ensure sufficient power to detect a significant difference in our primary outcomes given a moderate effect size of $d=0.30$ (estimated based on mean differences in use of trained skills reported by Wissow et al., 2011) and aiming at 80% power to detect an effect at the PCP level with a standard deviation of 0.5, we aimed to recruit a total sample of 50 PCPs. Adjusting for clustering using an inflation rate of approximately 15%, and an attrition rate of 7% (Wissow

et al., 2011; also see, Dumville, Torgerson, & Hewitt, 2006) our sample size target is 61 PCPs, which is consistent with the target sample size of a previous common skills training trial for PCPs (Wissow et al., 2011).

The target sample size of $N = 250$ families is based on Wissow et al., (2008) and represents the sample size needed at follow-up in order to detect moderate effects in the primary outcome (SDQ) for children ranging from 0.2 to 0.4 using two-tailed tests with $\alpha = 0.05$ and power = 0.80, while accounting for anticipated intra-cluster correlations between .01 to .05 (Murphy, Esterman, & Pilotto, 2006).

Analyses

Simple bivariate statistics will first be explored between intervention status and the outcome variables. We will then test the hypothesis that compared to TAU, PCPs in the intervention group will demonstrate enhanced mental health care capacity, and that children/youth will demonstrate improved mental health functioning. Multilevel modeling with random effects will be used to compare the two groups on all of the PCP and patient outcome variables. Multilevel modeling accounts for clustering of PCPs within sites, and patients within PCPs (Hussey & Hughes, 2007). In the case of data that are missing at random, multiple imputation will be carried out.

Hierarchical modeling will also be used to test whether gender, age, time in practice, baseline attitudes, perceptions of influence of workplace characteristics (IWCS) on mental health practice, or perceptions of influence over work (PIWS) moderate or mediate the effect of intervention status on post-intervention mental health care capacity. To test for mediation effects, after accounting for baseline confidence and skills in the first block, these potential mediators will be added in a second block. To test for moderation of intervention effects by baseline attitudes, the interaction terms between baseline attitudes and post-intervention confidence and skills will be entered into separate models, after accounting for baseline confidence and skills. In the same manner, we will examine whether the parent's/youth's age, gender, satisfaction with the visit (SWVS), or the degree to which the youth discussed sensitive topics (DSTS), mediates or moderates the effect of intervention status on child mental health functioning (SDQ) at four-month follow-up.

Intention-to-treat principles will be applied such that evaluation data will be collected from participants, to the extent possible, regardless of whether or not intervention participants complete the intervention. Data from these participants will be included in the analyses according to their original allocation status.

Qualitative data will be coded with NVIVO into key themes associated with aspects of the intervention PCPs found most/least acceptable/useful, and suggested ways in which the program/trial should be modified for future implementations.

Ethics

The University of Western Ontario's Research Ethics Board (REB) approved the procedures for this study (REB# 106397). Written consent from individual practitioners at each of the sites will be obtained in person by study personnel. Parents will provide consent to participate, as well as assent for their children under the age of 12. Youth over the age of 11 will provide consent to participate. Participants will be provided with a copy of their consent/assent form, which includes information on reporting any adverse events (e.g., significant mental health concerns reported by parent/youth at follow-up) to the REB. Parents/youth reporting any significant mental health concerns will also be provided with mental health resources and will be encouraged to speak with their PCP.

Discussion

Although educational intervention represents a key pathway to improving mental health care capacity in primary care, little evidence exists to direct what should be taught and how, or to indicate whether these interventions are effective for improving care and outcomes for children/youth.

We used findings from our national needs assessment with rural PCPs (Steele et al., 2012; Zayed et al., 2016), and a recent mental health knowledge-translation model (Brown & Wissow, 2012) to inform the structure and content of the PTCAP program. The design of this pilot trial, based on the common skills trial conducted by Wissow et al., (2011), includes a gold-standard, cluster-randomized research design and objective, observational assessment of trained skills. As such, this trial will provide strong evidence regarding the efficacy of the PTCAP program for improving mental health care capacity in primary care and well-being in children/youth. The trial will also provide critical information in regards to mechanisms of change.

Qualitative data from this study will provide important information in regards to acceptability and feasibility of the intervention and trial, clarifying which aspects of the trial/program worked best, for which PCPs. Findings will be utilized to improve knowledge translation efforts in paediatric mental health care for PCPs and other non-specialists, and to strengthen systems of mental health care for children, youth and their families living in underserved areas.

Limitations

While several strengths of this study are notable, including a randomized-controlled design accounting for clustering effects and an observational measure of mental health care skills and retention at one-month follow-up, we anticipate certain challenges that may pose a threat to the internal validity of the trial. For instance, we expect some challenges recruiting busy PCPs to participate in the intervention and evaluation. To overcome this potential challenge, we will encourage participation by offering flexible scheduling of training sessions, Mainpro M1 credits for participation and opportunities for psychiatric consultation after the intervention. In addition, we also anticipate some challenges recruiting patients; however, we will offer \$20 per assessment as an incentive and will encourage PCPs and administrative staff to recruit five patients per participating PCP. Another potential threat to internal validity may arise due to contamination (exposure of the control groups to the PTCAP intervention). We will minimize this threat through randomization at the cluster level rather than within sites. Finally, potential bias due to attrition will be addressed through the adoption of intention-to-treat principles in the analyses.

Conclusions

The PTCAP intervention is designed to support PCPs in providing frontline mental health care by combining standard teaching of practice guidelines for managing diagnosable mental health conditions, with teaching of brief counseling skills (i.e., common skills/elements) for addressing more general concerns (or while waiting on diagnosis/referral). This paper represents the protocol for the first,

cluster-randomized pilot of this novel educational intervention for rural PCPs. As one of the first RCTs of its kind in Canada, this study will provide unique, preliminary evidence in regards to the feasibility and efficacy of a novel educational intervention designed to enhance paediatric mental health care capacity in rural primary care.

Acknowledgements/Conflicts of Interest:

We would like to thank the Children's Health Foundation for their generous and longstanding support of the PTCAP educational initiative. Also, special thanks to Dr. Larry Wisow for his helpful input on our study design. As part of a team who developed the PTCAP program (SE, SG & MS), there is a potential conflict of interest in that we are also evaluating the program. To redress this, MS will only be involved in the delivery of the program and not in its evaluation. SG will allocate the sites to intervention or control blind to practice identity, and SE will carry out the analyses blind to practice identity and allocation status. The authors have no financial relationships to disclose.

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