Impact of wait times for treatment on clinical outcomes in patients with obstructive sleep apnoea: protocol for a randomised controlled trial

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Shareable abstract (@ERSpublications)
This study will determine whether expedited care for OSA leads to differences in PAP adherence and/or patient-reported outcomes https://bit.ly/38TrkwS

Cite this article as: Thornton CS, Povitz M, Tsai WH, *et al*. Impact of wait times for treatment on clinical outcomes in patients with obstructive sleep apnoea: protocol for a randomised controlled trial. *ERJ Open Res* 2022; 8: 00068-2022 [DOI: 10.1183/23120541.00068-2022].

Received: 3 Feb 2022
Accepted: 2 May 2022

Abstract

Background Obstructive sleep apnoea (OSA) is a common chronic condition that is associated with significant morbidity and economic cost. Prolonged wait times are increasingly being recognised as a barrier to diagnosis and treatment of many chronic diseases; however, no study to date has prospectively evaluated the impact of wait times on health outcomes in OSA.

Objective The purpose of this study is to determine whether treatment outcomes for individuals with OSA differ between patients managed using an expedited *versus* standard pathway.

Methods A pragmatic randomised controlled trial design will be used with a target sample size of 200 adults. Participants with clinically significant uncomplicated OSA will be recruited through referrals to a large tertiary care sleep centre (Calgary, AB, Canada) and randomised to either early management (within 1 month) or usual care (~6 months) with a 1:1 allocation using a concealed computer-generated randomisation sequence. The primary outcome will be adherence to positive airway pressure (PAP) therapy at 3 months after treatment initiation. Secondary outcomes will include change in sleepiness, quality of life, patient satisfaction, and patient engagement with therapy from baseline to 3 months after PAP initiation, measured using validated questionnaires and qualitative methods.

Anticipated results This study will determine whether expedited care for OSA leads to differences in PAP adherence and/or patient-reported outcomes. More broadly, the findings of this study may improve the understanding of how wait time reductions impact health outcomes for other chronic diseases.

Introduction

Background

Obstructive sleep apnoea (OSA) is a highly prevalent chronic condition with significant medical burden on both an individual and population level. Globally, the estimated prevalence of OSA, as defined by an apnoea–hypopnoea index (AHI) of $\geqslant$5 events·h^{-1}, is nearly 1 billion individuals [1]. The number of individuals with moderate to severe OSA, for whom treatment is recommended, is estimated to be >400 million [1]. OSA is associated with poorer quality of life, increased cardiometabolic risk, more frequent motor vehicle collisions and greater and more costly use of the healthcare system [2–5]. The annual cost of diagnosing and treating OSA is approximately USD 12.4 billion, with the estimated economic cost of untreated OSA of USD 150 billion per year [6].

Treatment of OSA improves health outcomes and is cost-effective [7, 8]. However, there are barriers to effective diagnosis and treatment, including under-recognition [9–12], variability in provider knowledge and supply–demand imbalance leading to long delays for care [13–15]. Based on expert opinion, Canadian clinical practice guidelines recommend a maximum wait time of 6 months for investigation of suspected OSA [16], and the American Academy of Sleep Medicine has suggested that severity should be confirmed within 2 months of initial evaluation [17]. However, wait times far exceeding these recommendations are reported in many jurisdictions [8, 14, 15], highlighting the importance of alternative approaches to diagnosis and treatment initiation.

Currently, there is sparse literature describing the clinical impacts of reducing wait times for OSA care. In a single randomised trial, immediate polysomnography compared to polysomnography after 6 months was associated with greater improvements in symptoms and quality of life at 6 months, and was cost-effective [18]. A notable limitation was that patients who were randomised to polysomnography at 6 months did not have PAP treatment, whereas those in the earlier group did, calling into question whether results were due to therapy alone. In a *post hoc* analysis from a randomised trial of respiratory therapist management of severe sleep disordered breathing, our group demonstrated that more timely initiation of positive airway pressure (PAP) therapy was associated with greater adherence to therapy [19]. This finding suggests that delayed care may change patient perceptions about the importance of sleep disordered breathing, modify patient behaviour (use of PAP) and result in poorer health outcomes. However, our study only included patients with severe sleep disordered breathing (including sleep hypoventilation); further confirmation is required in a more representative sample of uncomplicated patients with OSA.

Study objectives

The primary objective of this study is to evaluate the effect of more timely care for OSA on adherence to PAP therapy 3 months after treatment initiation. Secondary objectives are to determine if earlier care improves the treatment effect of PAP on patient-reported sleepiness, quality of life and patient satisfaction. We will evaluate how expedited care impacts patient engagement in therapy by assessing initial acceptance of PAP therapy, patient activation and self-efficacy with respect to OSA treatment. Finally, we will conduct focus groups with patients to explore their perspectives on the relationship between wait times and treatment adherence.

Methods

Study design

The proposed study is a pragmatic randomised trial in which patients with OSA diagnosed using home sleep apnoea testing (HSAT) will be randomised to either an early management strategy (clinical assessment within 1 month of HSAT) or usual care (clinical assessment ∼6 months after HSAT) (figure 1). This study is registered at www.clinicaltrials.gov with identifier number NCT04613414.

Study setting

The study will be conducted at the Foothills Medical Centre (FMC) Sleep Centre, a publicly funded, tertiary academic sleep centre in Calgary (AB, Canada), with a catchment of ∼2 million people. The FMC Sleep Centre receives ⩾2500 referrals annually, of which 46% are for OSA [20]. As part of the triage process, all newly referred patients undergo a one-night HSAT (Remmers Sleep Recorder, Sagatech Inc.) and complete a questionnaire that explores sleep symptoms and medical history. The results of the HSAT and questionnaire are reviewed by a provincially registered respiratory therapist using a physician-approved triage protocol to ensure that there is a clinical suspicion of OSA and to assign triage urgency. The entire triage process (HSAT, questionnaire and review) is typically completed within 1 month of referral, after which patients are scheduled for assessment by a sleep physician or nurse practitioner.

At the initial clinic visit, the care provider and patient establish a management plan that typically involves ambulatory PAP titration for individuals with uncomplicated OSA; PAP is usually prescribed at the initial visit and initiated within 1 week. Patients who are medically complex or with severe nocturnal hypoxaemia suggesting hypoventilation may be referred for polysomnographic PAP titration before initiating therapy. Follow-up is typically delegated to alternative care providers (ACPs); at the FMC Sleep Centre, ACPs are registered respiratory therapists who have completed a 3-year accredited training programme in Canada and have ⩾5 years of experience assessing and managing patients with OSA. Follow-up assessments are defined by a physician-approved protocol that complies with provincial practice regulations for registered respiratory therapists. Services include therapy education, support for patients with difficulty tolerating therapy, small adjustments to PAP to improve adherence and ordering of HSAT. Patients may be referred back to sleep physicians for management of issues outside of the ACP's scope of practice, a model with demonstrated efficacy [21]. All sleep diagnostic test interpretations and treatment prescriptions are

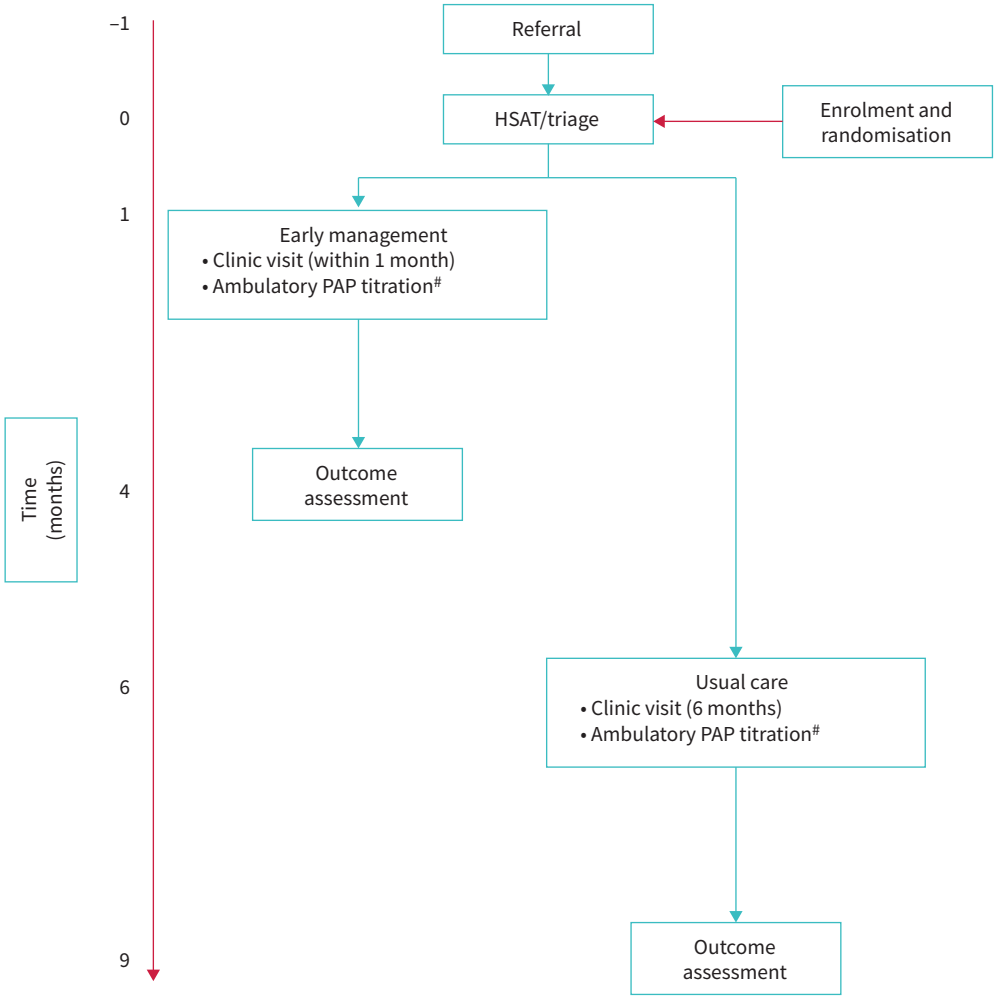

FIGURE 1 Study design flow: recruitment and data collection. HSAT: home sleep apnoea test; PAP: positive airway pressure. #: ambulatory PAP titration typically occurs within 1 week of clinic assessment, but patients with significant cardiopulmonary comorbidity may be referred for polysomnographic PAP titration at the discretion of the sleep physician (unlikely to be required based on eligibility criteria).

completed by sleep physicians. Testing is provided at no charge. Therapeutic options include lifestyle modifications, use of mandibular advancement devices and/or PAP. PAP therapy is provided by community-based respiratory homecare providers; costs for PAP therapy are borne by the patient (out-of-pocket or through private insurance) or through government programmes for individuals with low income.

Wait times for assessment at the FMC Sleep Centre vary depending on triage urgency. Patients with uncomplicated OSA typically wait between 6 and 12 months, while those with significant cardiopulmonary comorbidity or severe nocturnal hypoxaemia are deemed urgent and are assessed within 3 months. Polysomnography, if required for more complex cases, is typically completed within 1 month.

Eligibility criteria

Patients will be included if they are aged ⩾18 years and have clinically significant OSA diagnosed by HSAT with a 4% oxygen desaturation index (ODI). Clinically significant OSA will be defined as an ODI ⩾5 events·h^{-1} with excessive sleepiness (Epworth Sleepiness Scale (ESS) score ⩾10) or ODI ⩾15 events·h^{-1}. Patients will be excluded if any of the following criteria are met: severe nocturnal hypoxaemia on HSAT (mean peripheral oxygen saturation ⩽85%), severe hypersomnolence (ESS score ⩾16), safety-critical occupation, self-reported motor vehicle collision within 1 year, hypertension requiring three or more antihypertensive medications, hospital admission within 30 days of referral due to unstable

cardiopulmonary or cerebrovascular disease, upcoming major surgery within 6 months of triage, prior history of OSA treatment and/or significant comorbid sleep disorder that would interfere with CPAP acclimatisation and adherence. These exclusion criteria align with clinical guidelines recommending expedited care [16]. Patients meeting these criteria are at higher risk of complications of untreated OSA, raising ethical concerns with delaying care.

Study procedure

Potentially eligible patients will complete paper consents at the time of the HSAT appointment and eligibility will be confirmed by FMC Sleep Centre respiratory therapists at the time of triage review. Subsequently, participants will be randomised to either early management or usual care with a 1:1 allocation using a concealed computer-generated randomisation sequence. Participants randomised to early management will be scheduled for an appointment with a sleep physician or nurse practitioner within 1 month of HSAT date, whereas those randomised to usual care will be scheduled in 6 months. For feasibility, patients will be booked within 2 weeks of the desired timeframe. By virtue of the randomisation and scheduling process, the participants, research associate and booking clerks will be unblinded to allocation. Clinicians will not be informed of the study arm, but will have access to time-stamped referral information routinely available in patient charts.

After initial assessment, decisions regarding additional sleep diagnostic testing and treatment will be at the discretion of the patient and sleep physician/nurse practitioner as per usual practice. Based on current practice and study eligibility criteria, it is expected that most patients will be prescribed an ambulatory PAP titration at the time of the initial assessment and will not require polysomnography. Clinical follow-up at 3 months will be delegated to ACPs; duties will comply with current policy. Patients will receive automatically generated emails at 2 weeks, 1 month and 2 months after PAP initiation to identify problems with therapy. All email responses will be reviewed by the study team and forwarded to ACPs as required.

Data collection

The timeline of data collection is outlined in table 1. Patient demographics, symptoms, patient-reported comorbidities and medications, ESS score and HSAT data will be obtained at the initial visit. Nightly PAP usage data and residual OSA on therapy are recorded on PAP devices and transmitted to cloud storage operated by the manufacturer or stored on a removable chip in the device. After 1 week and 3 months of therapy, PAP data will be obtained from cloud storage or from the patients' provider. Each participant will complete six different questionnaires, as follows.

ESS: the ESS is a validated patient-reported measure of daytime sleepiness and will be used to evaluate OSA symptom severity at baseline and 3 months [22]. The ESS includes eight questions assessing how

TABLE 1 Timeline of data collection

	Baseline[#]	Follow-up[¶]
Demographics (age, sex, BMI, patient-reported medical comorbidity and medication use, patient-reported psychological comorbidity,[+] residence location by postal code and education level, household income, regular bed partner)	X	
Funding source for PAP (government, private insurance or out-of-pocket)	X	
Sleep study (REI, AHI, ODI, nocturnal S_{pO_2})[§]	X	
PAP adherence (machine download)		X
Epworth Sleepiness Scale	X	X
Visit-Specific Satisfaction Instrument	X	X
EuroQOL-5D-3L	X	X
Sleep Apnea Quality of Life Index	X	X
Patient Activation Measure	X	X
Self-Efficacy Measure for Sleep Apnea	X	X
Focus group		X

BMI: body mass index; PAP: positive airway pressure; REI: respiratory event index; AHI: apnoea–hypopnoea index; ODI: oxygen desaturation index; nocturnal S_{pO_2}: mean and nadir nocturnal oxygen saturation. [#]: baseline data will be collected from consenting patients at the time of initial visit; [¶]: follow-up data will be collected after 3 months of treatment with PAP; [+]: including claustrophobia, depression and/or anxiety; [§]: if a patient undergoes polysomnography, OSA severity will be reported from the home sleep apnoea test, and we will report the number of patients undergoing polysomnography.

likely a patient is to fall asleep in different scenarios on a scale of 0 to 3, with a higher score indicating more severe sleepiness.

Visit-Specific Satisfaction Instrument (VSQ-9): patient satisfaction is an important determinant of adherence to PAP therapy [23]. The VSQ-9 is a simple, validated, nine-question tool to measure patient satisfaction during an outpatient visit [24]. It has been used in prior studies evaluating care delivery models for OSA [25, 26].

EuroQOL-5D (EQ-5D-3L): the EQ-5D-3L is a standardised instrument used to measure general health-related quality of life. Quality-of-life scores are obtained by combining patient ranking of level of impairment in general health areas such as mobility and mood with an overall visual analogue scale of quality of life [27].

Sleep Apnea Quality of Life Index (SAQLI): the SAQLI is a validated disease-specific health-related quality-of-life questionnaire that identifies symptoms and functional impairment in five domains: daily functioning, social interactions, emotional function, symptoms and treatment-related symptoms. The SAQLI is sensitive to changes experienced by patients and is preferred over other disease-specific health-related quality-of-life measures for OSA because it includes a domain for treatment-related effects [28, 29].

Patient Activation Measure (PAM): the PAM is a validated tool to assess patient activation in self-management. The PAM is based on four stages: believing an active patient role is important; possessing the necessary confidence and knowledge to act; taking action to maintain and improve health; and staying the course under stress [30, 31]. The PAM score can be used to categorise patients into levels of activation that correlate with health outcomes and has been used in prior studies of interventions to improve PAP adherence [32].

Self-Efficacy Measure for Sleep Apnea (SEMSA): the SEMSA is a validated disease-specific tool, drawn from social cognitive theory, that evaluates perceptions of risks to health, expectations of treatment outcomes and confidence to engage in health-promoting behaviour. The SEMSA identifies patients at risk of PAP nonadherence and was selected to assess factors that may mediate the relationship between wait times for care and treatment adherence [33].

Additional questions exploring other aspects of the participant's OSA history and care will be included (supplementary material); we have used these questions previously to assess duration of OSA symptoms before seeking care, wait times for care, perceptions about wait times for OSA care and impact of OSA on work or school attendance and productivity [34, 35].

Participants will have the option of completing questionnaires electronically or on paper. Participants will be sent an emailed questionnaire link at baseline and after 3 months of therapy. Those who do not complete follow-up questionnaires will be sent automatic e-mail reminders weekly for 4 weeks. If the online questionnaire has not been completed by time of follow-up appointment, a paper copy will be provided at that visit.

Finally, we will conduct semi-structured focus groups to explore patient perspectives on wait times for OSA care, the impact of delays for care on treatment outcomes and how expedited care affects patient engagement and treatment adherence. At the end of the study, patients from each arm will be invited to participate in focus groups (supplementary material).

Data analysis

Descriptive statistics will be used to report baseline characteristics. Study outcomes in the early management and usual care groups will be compared 3 months after PAP initiation using t-tests or Mann–Whitney U-tests for analysis of continuous variables, as appropriate. Chi-squared tests will be used to compare binary variables. The primary outcome will be the mean number of hours of PAP use per night in the 4 weeks prior to the 3-month follow-up, measured as a continuous variable.

Secondary outcomes will include the proportion of patients who do not initiate PAP therapy; the proportion of patients using PAP therapy for $\geqslant$4 h per night on $\geqslant$70% of nights during the 4 weeks prior to the 3-month follow-up [36]; change in ESS from baseline (initial clinic visit) to 3 months after PAP initiation; change in EQ-5D-3L visual analogue score from baseline to 3 months after PAP initiation; change in SAQLI from baseline to 3 months after PAP initiation; VSQ-9 total score compared between

groups at baseline and after 3 months of PAP therapy; change in PAM score from baseline to 3 months after PAP initiation; change in patient activation level from baseline to 3 months after PAP initiation; SEMSA score compared between groups at baseline and after 3 months of PAP therapy; and patient perceptions about wait times for diagnosis and treatment, compared between groups.

Multiple linear mixed-effect models will be used to assess the relationship between study allocation and PAP adherence. Based on prior literature [37] and consensus of the study investigators, model covariates will include age, sex, household income, education level, baseline OSA severity, body mass index, duration of symptoms prior to seeking medical attention, actual time to PAP initiation, PAP type, use of polysomnography for PAP titration, initial provider (physician *versus* nurse practitioner), baseline sleepiness, quality of life, psychological measurements (*e.g.* cognitive and motivational knowledge, self-efficacy, perceived risk of OSA), PAP pressure and side-effects and first week of PAP therapy use as a surrogate for early adherence [38].

Focus groups will be recorded, transcribed verbatim and coded by two study team members using the NVivo software platform. These study team members will use an inductive approach to identify themes and subthemes from the qualitative data, first independently and then through regular meetings to achieve consensus.

Sample size

The study hypothesis is that early management strategy will be superior to usual care with respect to the primary outcome of PAP adherence at 3 months. Based on a minimum clinically important difference of 0.5 h per night [39], standard deviation of 1 h, two-sided α=0.05 and power of 0.9, a sample of 126 (63 in each arm) will be required. To account for dropouts and patients treated with non-PAP therapies, 200 patients will be recruited. Focus groups will consist of 20 participants, although this may be adjusted to achieve data saturation. Current referral volume at the FMC Sleep Centre indicates that recruitment will be completed within 1 year.

Ethics

Research ethics approval

Ethics approval was obtained from the Conjoint Health Research Ethics Board (CHREB ID: REB20–1667) at the University of Calgary. The ethics approval process involved reviewing the study with respect to content and compliance with applicable research and safety regulations. In addition to initial approval, CHREB will review the study on an annual basis.

Consent or assent

Study participants will complete an informed consent form prior to initial questionnaires at the time of the first visit. The form outlines the study objectives and details, including risks and benefits, and was written at a grade 9 reading level using Hemingway (www.hemingwayapp.com). Patients will be notified if they are eligible based on HSAT results and can withdraw at any time, either completely or for questionnaires only. Data contributed up to the point of withdrawal will be retained and if a participant withdraws from questionnaires only, we will collect PAP download data at 3 months.

Data storage and confidentiality

All electronic and paper study data will be stored according to the University of Calgary's information and security policy. Paper data will be entered into the Research Data Capture platform. PAP adherence downloads and other patient data will be stored securely and in accordance with the University of Calgary research ethics board requirements. Random audits of study data will be performed at regular intervals for quality assurance purposes. Electronic study data will be maintained on secure, password-protected and encrypted servers behind the University of Calgary firewall.

Anticipated results, dissemination and knowledge translation

Delays for OSA care are widespread and may lead to adverse health outcomes by prolonging exposure to untreated disease or by hindering patient engagement with therapy. This project will clarify whether an early management strategy improves treatment adherence and patient-reported outcomes compared to usual care that incorporates delays. This study will quantify the impact of timely management of OSA on PAP adherence and patient-reported outcomes. Although patients identify wait times for OSA care as problematic [40], there is limited research exploring whether expediting care improves OSA outcomes. Furthermore, wait time reduction strategies may have significant downstream cost and resource implications. Prior evidence in a more complex patient population suggests that shorter wait times could modify perceptions about the urgency of OSA treatment, leading to greater adherence and improved

outcomes [19]. To prioritise an OSA wait times reduction strategy, these findings must be confirmed prospectively in a more generalised population of patients. The results of this study will support the development and implementation of efficient models of OSA care and inform clinical guidelines for optimal care of patients with OSA. More broadly, the findings of this study may improve the understanding of how wait time reductions impact health outcomes for other chronic diseases and inform future research and quality improvement initiatives.

Provenance: Submitted article, peer reviewed.

This study is registered at www.clinicaltrials.gov with identifier number NCT04613414. Anonymised individual participant data and study documents can be requested for further research from the corresponding author.

Conflict of interest: C.S. Thornton reports receiving grants or contract fees from Cystic Fibrosis Foundation Postdoctoral Funding, outside the submitted work; and support for attending meetings and/or travel received from a Cystic Fibrosis Foundation Postdoctoral Scholarship, outside the submitted work. M. Povitz reports support for the present manuscript received from The Lung Association; grants or contracts received from Zennea Corporation and Jazz Pharma, outside the submitted work; consulting fees received from Rebel Sleep Company, Jazz Pharma and Paladin labs, outside the submitted work. A.H. Loewen reports support for the present manuscript received from The Lung Association. T. Kendzerska reports receiving consulting fees from Pitolisant Medical, outside the submitted work; and a speaker honorarium from AstraZeneca Canada Inc., outside the submitted work. W.W. Flemons reports support for the present manuscript received from The Lung Association; grants received from CIHR outside the submitted work; and consulting fees received from Healthy Heart Sleep Company and MedPro Respiratory Care, outside the submitted work. P.J. Hanly reports receiving grants or contracts from The Lung Association, Alberta and NWT, outside the submitted work; consulting fees received from Dream Sleep Respiratory services, outside the submitted work; and participation on an Advisory Board for Jazz Pharmaceuticals, Eisai Ltd (pharmaceutical company), Paladin Labs Inc (pharmaceutical company), and Sleep Medicine Diagnostics, College of Physicians and Surgeons of Alberta, Canada, outside the submitted work. S.R. Pendharkar reports support for the present manuscript received from The Lung Association; and grants or contracts received from Canadian Institutes of Health Research, MITACS, Alberta Health Services, and University of Calgary, outside the submitted work. Consulting fees received from Jazz Pharmaceutical, and Paladin Labs, outside the submitted work. The remaining authors have nothing to disclose.

Support statement: This study was supported by The Lung Association of Alberta and Northwest Territories National Grant Review. Funding agencies had no role in study design, analysis or interpretation of results. Funding information for this article has been deposited with the Crossref Funder Registry.

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