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Research Article

Protocol for Alberta Societal Health Integration Program (ABSHIP): Community-based Acupuncture Services Model for Social Recovery and Improve Economic Participation

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Abstract

Background: Mental health problems and chronic health conditions cause significant productivity loss in the workplace. Existing chronic pain and mental healthcare needs in Canada before COVID-19 remain unmet and have been exacerbated by the pandemic. The Alberta Societal Health Integration Program (ABSHIP) proposes an innovative community-based model in which acupuncture services are provided to improve social recovery and economic participation.

Methods: Participants received a minimum of two acupuncture treatment sessions per week up to a total of 12 treatments. The study recruited 150 participants between the ages of 14 and 55 who were suffering from pain or mental health issues which caused severe productivity loss. Primary outcome indicators used included productivity (WPAI), pain (BPI), quality of sleep (PSQI), depression (PHQ-9), anxiety (GAD-7), anger (DAR-5), quality of life (EQ-5D-5L) and substance use (DAST-10 & CAGE). Secondary outcome indicators included general health care utilization measured through patients' self-reported inpatient, outpatient, emergency department, and prescription drug utilization. Data was collected at baseline (before treatment) and following the sixth and twelfth sessions (post-treatment). In order to understand long-term impacts of ABSHIP, participants were invited to take the same survey after three and six months following completion of the program.

Discussion: ABSHIP is a first-of-its-kind study that provided integrated acupuncture interventions to enhance pain management while protecting and fostering psychosocial well-being and resilience in children, adolescents, and seniors. The evidence generated from this project will shed light on the effectiveness and cost The evidence generated from this project will shed light on the utility and cost-effectiveness of integrative care in pain and mental health management.

Trial Registration: This interventional study has been approved by the University of Calgary (UofC) Conjoint Health Research Ethics Board (CHREB) (ethics ID: REB 21-2050).

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Abbreviations

ABSHIP: Alberta Societal Health Integration Program

CHREB: Conjoint Health Research Ethics Board

CRU: Clinical Research Unit

PHN: Personal Health Number

AHS: Alberta Health Services

COPD: Chronic Obstructive Pulmonary Disease

WPAI: Work Productivity and Activity Impairment questionnaire

BPI: Brief Pain Inventory

PSQI: Pittsburgh Sleep Quality Index

PHQ-9: Patient Health Questionnaire 9

GAD-7: Generalized Anxiety Disorder 7

DAR-5: Dimensions of Anger Reactions 5

EQ-5D-5L: EuroQol 5 Dimension 5 Level

CAGE: Cut, Annoyed, Guilty, and Eye

DAST-10: Drug Abuse Screening Test 10

Background

During the pandemic caused by coronavirus disease 2019 (COVID-19), global public health measures were implemented to

prevent spread of infection [1]. In March 2020, wide-scale emergency measures were implemented in Canada which drastically limited Canadians' capacity to engage in employment, educational, recreational, and social activities [2]. As a result, a wide variety of issues such as stress, anxiety, frustration, and isolation negatively impacted the health and well-being of Canadians. Impacts on sleep, nutrition, substance use, and other areas of health led to worsening of existing chronic and mental health conditions [1,2]. In addition, economic recession related job and income losses could have further triggered substance abuse and mental health crises [3-8].

According to a 2015 RAND corporation study, the following factors caused significant productivity loss in the workplace: mental health problems, lack of sleep, and chronic health conditions [9]. Specifically, chronic pain is a common health problem with a global economic impact; for example, headaches, neck tension and discomfort, and lower back pain are believed to cause lost productivity [9-12]. Furthermore, numerous studies have indicated further exacerbation of chronic pain and lower back pain during the COVID-19 pandemic [12-14]. Increased work from home employment may have contributed to musculoskeletal pain; individuals who engaged in remote work or distance learning during COVID-19 reported increased neck or lower back discomfort [13,15]. In addition to shifts in working practices, government directives for individuals to remain at home and social distance may have resulted in decreased rates of physical activity and increased rates of psychological stress [16-19]. Chronic pain has been highly correlated with low levels of physical activity and the presence of psychological disorders [20-22]. These changes in working habits and physical activity patterns, as well as the increase in psychological stress caused by COVID-19 may have influenced and/or exacerbated pain symptoms for individuals with existing chronic pain.

The COVID-19 pandemic has had significant and long-lasting impacts on the mental health and wellbeing of Canadians [23,24]. Individuals reporting low incomes, unemployment, or loss of employment during the pandemic reported higher rates of anxiety, depression, suicidal ideation, and substance use [25, 26]. These factors not only worsen the condition of previously healthy individuals but also deteriorate the mental health of individuals with pre-existing issues. Additionally, the economic recession following the pandemic would likely have a disproportionately negative impact on socially disadvantaged individuals, furthering existing healthcare inequities [27]. These unmet social determinants of health and unmet mental healthcare needs that existed in Canada before COVID-19 persists within the current system, according to the Canadian Mental Health Association [23].

The effectiveness of acupuncture in treating chronic pain, mental stress, anxiety, depression, and substance abuse has been previously demonstrated [28-37]. To cope with arising pain and mental health needs in the aftermath of the COVID-19 pandemic, urgent intervention is needed. Pursuant to this, we proposed the development of the Alberta Societal Health Integration Program (ABSHIP). ABSHIP is a novel, community-based, and cost-effective acupuncture service model that may improve mental health outcomes and overall well-being, enhance productivity and economic participation, and ultimately facilitate social recovery. The acupuncture services offered in this program adopt a holistic approach and emphasize general health rather than specific illness states. Therefore, the objective of ABSHIP is to mitigate, treat, and prevent mental health and pain-related issues arising from the COVID-19 pandemic and promote community integration, overall productivity, and economic participation through holistic development and continued well-being.

Methods

Treatment regimen

In ABSHIP, acupuncture treatment protocols will be designed based on established evidence and clinical expertise from local and international acupuncture experts. The acupuncture treatment plan for a single complaint typically lasts one to three months, involving a minimum of two treatments per week by licensed practitioners. The number of treatments will depend on the condition being treated and its severity, up to a total of 12 treatments provided. Participants will not need to pay for the interventions they receive in ABSHIP.

To determine the type of acupuncture treatment that will benefit the participant the most, the practitioner will ask questions about their symptoms (e.g. sleeping, digestion) and lifestyle (e.g. diet), and conduct physical examinations including examination of sites of pain; shape, coating, and color of the participant's tongue; color of the participant's face; and strength, rhythm, and quality of the pulse in the participant's wrist. Based on these examinations and discussions of the patient's expectations and treatment goals, the practitioner will propose an individualized acupuncture treatment plan for the patient, using the established treatment protocols as a guideline (35, 36).

Study population and inclusion criteria

Patients between the ages of 14 and 55 who meet the following criteria will be included in our study:

1. Student, employed, or unemployed and searching for work;
2. Has not received acupuncture treatments within the last 3 months;
3. Has at least one listed concern or condition, including:

- Mental health concerns and/or conditions (e.g. sleep disorders, anxiety, depression, fatigue, burnout, post-traumatic stress disorder, etc.)
- Chronic pain, acute pain, or pain management issues.

The above conditions were chosen because these factors have been shown to cause significant productivity loss and have well-established therapeutic improvements with acupuncture.

Exclusion criteria

We will exclude children under the age of 14 and those above 55 years old. Children under the age of 14 will be excluded because compliance with acupuncture treatment, especially acupuncture treatment, is very low among younger children. Adults over the age of 55 will be excluded because our program iis focused on enhancing workplace or educational productivity. Additional exclusion criteria include:

1. Those who do not give or withdraw their consent;
2. Children whose parents or guardians do not give or withdraw their consent;
3. Those who have received acupuncture within the last 3 months

4. Those who are not comfortable receiving acupuncture or cannot meet the minimum treatment frequency requirement.

Recruitment procedures

Our study targets Albertans facing challenges with mental health and/or well-being including chronic pain, acute pain, or pain management issues. A total of 150 patients will be recruited for the study. Patients will be recruited through public outreach efforts including a publicly accessible study website (https://www.abship.ca/) and posters and fliers placed in acupuncture and primary care clinics to attract potential participants. Additionally, the project aims to increase program outreach by enlisting the help of civil society organizations and conventional physicians to recruit participants. Civil society organizations will distribute ABSHIP project information so that potential participants can contact the research team if they are interested. To further reach those in need, the project will also seek to collaborate with primary care physicians, psychologists, and psychiatrists.

Data collection

We will collect comprehensive information on participants' well-being using validated survey instruments in areas including: Mental health (anxiety, depression, fatigue, anger); Pain, and sleep quality; Quality of life; Health care utilization; Return to work / School (employment / school status, weekly hours of paid work, days of absence from work / school, and return-to-work or school date) (Table 1). This data will be collected via and stored on REDCap, a secure web application for building and managing online surveys and databases. REDCap is hosted by the Clinical Research Unit (CRU), a core research support center at the University of Calgary.

At the end of the first consultation session, the participant will be asked to complete a questionnaire collecting basic demographic information such as age, gender, and Alberta Personal Health Number (PHN) and health information regarding chronic pain, addiction, mental health, and quality of life. Participant's medical records will not be accessed at this stage.

Following the 6th and 12th treatment sessions, the participant will be asked to complete another questionnaire collecting health information on chronic pain, mental health, addiction, and quality of life for the purpose of treatment effect monitoring and outcome evaluation. This will help estimate short-term results of the ABSHIP program. Participants will receive emails inviting them to complete the same surveys through REDCap three months and six months following their last treatment in order to evaluate long-term impacts of the study.

Information collected throughout the study will be utilized to establish an ongoing database to monitor and evaluate the mental health and well-being, quality of life, and social recovery of program participants. This database will have the potential to be linked to administrative healthcare records within Alberta Health Services (AHS) databases to enable correlational research to healthcare utilization. This would further allow us to generate evidence that would inform both service providers as well as policy makers, and better meet the recovery-oriented needs of the Alberta population.

Outcome measures

The primary outcome variables include participant-reported productivity, pain, quality of sleep, mental health, and quality of life. Productivity will be measured using the Work Productivity and Activity Impairment questionnaire (WPAI). Pain will be measured using the Brief Pain Inventory (BPI) Short Form. The Pittsburgh Sleep Quality Index (PSQI) will be used to measure quality of sleep. Depression will be measured by Patient Health Questionnaire (PHQ-9) scores, anxiety will be measured using the GAD-7, anger will be measured using the DAR-5, and quality of life will be measured using the EQ-5D-5L. Substance use will be measured using CAGE & DAST-10 questionnaires.

The secondary outcome variable is defined as participants' general healthcare utilization. This will be measured by patient self-reported inpatient, outpatient, emergency department, and prescription drug utilization.

The outcome measures are illustrated in Table 1

Our primary outcome indicators are productivity, pain, quality of sleep, depression, anxiety, anger, and quality of life, which will be measured by changes in patients' WPA, BPI, PSQI, PHQ-9, GAD-7, DAR-5, and EQ-5D-5L scores, respectively. Substance use will be measured using the DAST-10 and CAGE questionnaires

Data analysis

Descriptive statistics including proportions and means with corresponding 95% confidence intervals (CI) will be used to describe each health outcome for the overall cohort and stratified for each demographic variable. Outcomes will be reported at baseline, during treatment (after 6th and 12th sessions), and after treatment (3-months & 6-months post-treatment). To compare outcomes between baseline and post-treatment, two-sided t-tests will be used to determine statistically significant differences in outcomes scores between timepoints.

In statistical modeling, we will also include demographic variables (age, sex, socioeconomic status, occupation), baseline health status (mental health and addiction), patient self-reported utilization of conventional care, and measures of acupuncture treatment received. These first-hand data collected from patient surveys will be used to conduct outcome and economic evaluations, including cost effectiveness and cost benefit analyses.

We will also translate the observed impacts into cost savings measured by both reduction in direct cost (i.e. hospital, physician, drug, research and other institutional care expenditures) and indirect costs (i.e. reduction of quality of life, lost production due to disability and premature mortality), using evidence from the economic burden of illness literature. Comparing the cost-benefit of the ABSHIP program will inform policymakers on potential cost saving from integrating conventional medicine and acupuncture within the healthcare system in both short-term and long-term scopes.

Ethics and Data Security

The Conjoint Health Research Ethics Board (CHREB), University of Calgary, has evaluated and approved this study. The researchers will take precautions to ensure the confidentiality of the participant's personal information. Although every effort will be made to

Measure	Instrument	Description
Productivity	Work Productivity and Activity Impairment Questionnaire (WPAI)	Productivity is assessed in terms of work time missed and job and activity limitations caused by a specific health issue over the previous seven days. The first portion of the question inquires as to how health issues may affect one's capacity for employment and participation in daily activities. The second section inquiries about academic performance.
Pain severity	Brief Pain Inventory (BPI)	Calculated from the mean of four pain intensity questions: pain at its "worst" in the prior week, pain at its "least" in the previous week, pain at its "average" in the preceding week, and pain "now." Answers to the four questions range from 0 to 10, with 0 indicating no pain and 10 indicating the most excruciating pain imaginable.
Pain interference	Brief Pain Inventory (BPI)	Calculated from the mean of seven questions regarding how much pain affects various aspects of everyday living including general activity, mood, walking ability, regular work (both inside and outside the home), relations, sleep, and life enjoyment. Responses to each question range from 0 to 10, with 0 denoting no interference with function and 10 denoting severe inhibition of function due to pain.
Sleep quality	Pittsburgh Sleep Quality Index (PSQI)	The scale consists of two parts: five questions that are rated by a bed partner (if applicable) and 19 self-reported questions that are used to rate sleep quality including: subjective sleep quality, sleep latency, sleep duration, habitual SE, sleep disruptions, usage of sleep medication, and daytime dysfunction. To get scores that correlate to the scale's domains, questions are evaluated from 0 (no difficulty) to 3 (extreme difficulty). A higher PSQI score indicates worse sleep.
Depression	Patient Health Questionnaire 9 (PHQ-9)	The PHQ-9 score is calculated from frequency of nine depressive symptoms, including feelings of hopelessness, a loss of interest in activities, and appetite loss, in addition to anxiety and alcohol use. A higher score on the PHQ-9 scale, which is scored from 0 to 27, suggests more severe depression.
Anxiety	Generalized Anxiety Disorder 7 (GAD-7)	From a self-reported seven item questionnaire, the GAD-7 measures the severity of various GAD symptoms. For each symptom, severity is scored as 0, 1, 2, and 3 for corresponding response categories of "not at all," "several days," "more than half the days," and "nearly every day." The total score is determined by the sum of all symptom scores with a higher score indicating worse anxiety.
Anger	Dimensions of Anger Reactions (DAR-5)	Dimensions of Anger Reactions (DAR-5) is a 5-item test that measures anger experience. The DAR-5 examines the frequency, intensity, duration, level of aggression, and influence on functioning of anger over the last four weeks.
Substance use	Cut, Annoyed, Guilty, and Eye (CAGE) & Drug Abuse Screening Test (DAST-10)	The CAGE questionnaire, which consists of four questions, is a screening tool for identifying alcohol use disorder. In addition, DAST-10 specifically asks about substance abuse other than alcohol, such as recreational drug usage and excessive prescription drug use. The patient responds with "yes" or "no" to each question, which corresponds to the last 12 months.
Overall Quality of Life	EQ-5D-5L	Mobility, self-care, routine activities, pain or discomfort, and anxiety or depression make up the five components of the questionnaire, with five degrees for each component: "no problems", "slight problems", "moderate problems", "severe problems" and "extreme problems." A health utility score from <0 (signifying health conditions worse than death) to 1 (signifying perfect health) is scored from the five responses.
Healthcare utilization	Self-reporting mechanism	Patients will self-report the dosage and frequency of their medication intake, in addition to how often they have had contact with different healthcare providers, hospitalizations, and ER visits in the previous week. To ascertain whether the visits and prescription consumption were related to the same problem for which ABSHIP therapy was initiated, inquiries will be made. For economic analysis, the typical number of ER visits and the anticipated number of hospital admissions will be considered.

Table 1: Descriptions and utilized instruments for primary and secondary outcome measures.

maintain participant data privacy, an inadvertent privacy breach is always possible. The study team will manage data in accordance with the following Data Management Plan.

The participant's personal contact information will be stored separately from their health information. Identifiable information about the participant will be replaced with a code. A master list linking the code and the participant's identifiable information will be kept separate from the research data. This master list will be kept under lock and key. In all arms of the study, all data will only be accessible by project team members, except for representatives of the CHREB and/or funding agencies for the purposes of quality assurance (i.e. to ensure that the study is being conducted in an ethical manner). In the case of an ethical review, these representatives will perform their duties under the supervision of the principal investigator. Except when professional rules of ethics or laws necessitate reporting, all material will be kept confidential. Paper documents will be held in a closed file cabinet on the University of Calgary campus, while electronic information will be retained on secure servers managed by the UofC and AHS. The REDCap data platform from the Clinical Research Unit (CRU) at the University of Calgary will be used for survey distribution and data storage. This is done for two reasons. First, the CRU has all necessary data sharing/storage

agreements with Alberta Health Services in place. Second, the CRU server is physically located on the University of Calgary campus, ensuring that all information provided is not subject to other stipulations such as the US Patriot Act. This overcomes major limitations of software and servers housed outside of Canada.

Discussion

The goal of this research is to create a community-based acupuncture service model that is both cost-effective and can effectively improve mental health and well-being. This model will have the potential to aid social recovery from the COVID-19 pandemic by improving general health (i.e., sleep, pain), mental health, quality of life, well-being, self-esteem, resilience, and social inclusion. Projects on this scale can further boost economic participation by lowering absenteeism and presenteeism among workers and encouraging workforce re-entry.

This initiative can assist in the development and implementation of a Science-Policy-Practice Network for social recovery in Alberta through promoting collaboration and complementary health integration with other health professionals, health organizations, community groups, and the general public. It also intends to reach out to other mental health agencies and recovery capitals to encourage greater implementation of this concept. It is feasible to integrate all these different resources and produce value through partnerships by testing an innovative, scalable, and transportable community-based acupuncture service model.

This program's conceptualization, execution, and evaluation framework might serve as a model for innovative service delivery and cutting-edge research in this field. This methodology might be extended across partnerships and could be expanded to include services such as detoxification and harm reduction centers.

However, there are two major methodological limitations of the evaluation plan of ABSHIP. First, as ABSHIP is not a randomized controlled trial and there is no control or placebo group. Second, health utilization is self-reported and subjected to reporting errors and recall bias. Given, ABSHIP is a first-of-its kind acupuncture integration and intervention project; rigorous outcome and health economics evaluation using real-world data from ABSHIP is crucial to generate policy implications. If this initiative is effective, the important lessons and knowledge gained from it might motivate the replication of such programs for other groups in Alberta, Canada, and throughout the world.

Ethics Approval

The Conjoint Health Research Ethics Board (CHREB), University of Calgary has reviewed and approved this research protocol (Ethics ID: REB 21-2050). All methods were carried out in accordance with relevant guidelines and regulations. Written informed consent will also be obtained from all study participants and their legal guardians/parents.

Competing Interests

The authors declare that they have no competing interests.

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