UOJM JMUO

July 2024
Volume 14.1

Updates in Family Medicine

Mises à jour en médecine familiale

ISSN: 2292-650X

UOJM
UNIVERSITY OF OTTAWA JOURNAL OF MEDICINE

JMUO
JOURNAL MÉDICAL DE L'UNIVERSITÉ D'OTTAWA

VOLUME 14 ISSUE 1 July 2024

The student-run medical journal of the University of Ottawa

ABOUT US

UOJM is an international peer-reviewed journal led and published by the students of the Faculty of Medicine. We welcome submissions in a variety of areas in biomedical research and feature original research, review articles, news and commentaries, case reports and opinion pieces. Our articles are written in both English and French. We are the only bilingual medical journal in Canada run by students.

Le JMUO est un journal revu, édité et publié par les étudiants de la Faculté de médecine. Nous encourageons les soumissions d'une variété de différents domaines en recherche biomédicale et publions des articles de recherche originale, des articles de revue, des nouvelles et commentaires, des rapports de cas et des pièces d'opinion. Nos articles sont écrits en français et en anglais. Nous sommes la seule revue médicale bilingue au Canada dirigée par des étudiants.

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TABLE OF CONTENTS

UOJM: PREFACE

For most of us, our conscious first contact with the medical community and healthcare system is through family medicine. Whether we are located within the heart of a vibrant city or in a peaceful rural community, family medicine is universally important. In health or disease, family medicine practitioners are present and actively involved in serving their patients, from birth through old age, making this one of the few specialties to establish such long-lasting and enduring doctor-patient relationships.

While the unmet and growing demands for access to family medicine care are ubiquitous,[1] this unique area of practice encompasses over 47,000 practicing physicians in Canada,[2] highlighting its significance in our healthcare ecosystem. In fact, increasing the number of family physicians per capita has been directly linked with measurable benefits in longevity and health outcomes.[3]As such, this area of practice is indisputably critical for the well-being of the Canadian population.

Arguably, a defining feature of family medicine is its breadth and scope of practice. In recognizing this, the topics covered in the current issue reflect this reality. We hope that this issue echoes the current challenges and exciting areas of development in family medicine. Here is an overview of what you can expect in this current issue:

TELEMEDICINE MANAGEMENT OF COPD: A BRIEF REVIEW OF ADVANCEMENTS IN CHRONIC DISEASE TREATMENT AND IMPLICATIONS FOR MEDICAL EDUCATION

Corrado and Hanycz highlight the importance and future potential of telemedicine in the management of COPD. Through lessons learned during the COVID-19 pandemic and ongoing COPD telemedicine efforts, the authors advocate for the formal introduction of telemedicine care in the curriculum of undergraduate and postgraduate medical education.

COVID-19 DERMATOLOGIC MANIFESTATIONS: ISSUES MORE THAN SKIN-DEEP

In this commentary, Pastukhova argues for more diverse and inclusive medical teaching of dermatologic conditions affecting individuals with skin of different colours. This topic is of current relevance, given that COVID-19-related dermatologic conditions are increasingly common as SARS-CoV-2 infections continue to be a reality in many regions across the world. This call to action is directly aimed to further our understanding of skin of colour dermatology in practice and teaching.

COMMUNICATION BARRIERS AND CHALLENGES FOR ACCESSING AUTISM CARE: CONVENTIONAL VERSUS ALTERNATIVE MEDICINE

Antoine presents findings of a study investigating the dynamics of communication flow between parents/caregivers of a child with autism with alternative and/or conventional healthcare providers. Using thematic analysis, this study offers insights into the use of alternative medicine in autism care, as well as identifying potential areas of improvement between all involved parties.

ISOPROPYL ALCOHOL AS ANTI-EMETIC THERAPY IN THE EMERGENCY DEPARTMENT: STUDY PROTOCOL FOR A MULTI-CENTER RANDOMIZED CONTROLLED TRIAL

Hamelin and colleagues present their protocol for a prospective randomized controlled trial into the usage of isopropyl alcohol as an anti-emetic therapy. As highlighted by the authors, nausea and vomiting are common occurrences in the emergency department and remain challenging to address. This study aims to validate and investigate earlier reports of isopropyl alcohol being an efficient anti-emetic treatment with minimal side effects in the context of emergency department care.

UOJM: PREFACE

QUALITY IMPROVEMENT OPPORTUNITIES FOR POST-DISCHARGE URINE CULTURE FOLLOW-UP IN A TERTIARY CARE EMERGENCY DEPARTMENT: A PILOT STUDY

Rajaram and colleagues present findings of a pilot study investigating and evaluating institutional quality assurance processes in the context of urine cultures ordered by the emergency department. Through the review of health records, the authors identified potential areas of improvement while quantifying delays in post-discharge urine cultures that required physician review.

RACIAL DISCRIMINATION DURING THE COVID-19 PANDEMIC AND MENTAL HEALTH OF YOUNG ADULTS: A CROSS-SECTIONAL STUDY OF UNIVERSITY STUDENTS FROM EAST ASIAN BACKGROUNDS

In a cross-sectional study, Rodriguez and colleagues investigated the impact of xenophobia and racial discrimination during the COVID-19 pandemic on East Asian university students' mental health. Using an online survey, the authors investigated the efficacies of coping strategies and ethnic/cultural identity stages on mental health.

USING POINT-OF-VIEW WEARABLE TECHNOLOGY AS A TOOL IN VIRTUAL TEACHING SESSIONS TO SUPPLEMENT CLINICAL SKILLS TRAINING: A MEDICAL STUDENT PERSPECTIVE

Sheng and colleagues investigated the use of wearable technologies as a tool in virtual teaching sessions for medical students. Given the fact that COVID-19 has resulted in disruption in medical education, with many schools shifting their preclinical curriculum online,[4] wearable technologies may represent a novel approach to managing the barriers to in-person teaching that have resulted from COVID-19. This study used point-of-view technology during an abdominal physical examination and gathered information on the student experience using questionnaires.

NON-PHARMACOLOGICAL INTERVENTIONS FOR THE TREATMENT OF RAYNAUD'S PHENOMENON: A SYSTEMATIC REVIEW

In a systematic review, Mahmood and colleagues analyzed and surveyed the literature regarding Raynaud's phenomenon in the context of non-pharmacological interventions. The authors contextualized their findings in the prevalence and potential etiology of this condition before doing a deep dive into the published literature, categorizing interventions and rating the quality of evidence for each. This systematic review highlights future areas of investigation into Raynaud's Phenomenon.

As Canada continues moving towards a post-pandemic setting, family medicine continues to be increasingly important for all Canadians. We are convinced that family medicine practitioners will continue to meet the challenge and lead the way to a healthier future.

On behalf of everyone at the University of Ottawa Journal of Medicine, we wish you a productive, innovative and fulfilling medical and research practice.

Yannick Galipeau
Co-Editor in chief (2023-2024)

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JMUO: PRÉFACE

Pour la plupart d'entre nous, notre premier contact conscient avec la communauté médicale et le système de santé se fait par le biais de la médecine familiale. Que nous soyons situés au cœur d'une ville dynamique ou dans une paisible communauté rurale, la médecine familiale est d'importance universelle. Qu'il s'agisse de la santé ou de la maladie, les médecins de familles sont présents et activement impliqués auprès de leurs patients, de la naissance jusqu'à la vieillesse, ce qui en fait l'une des rares spécialités à établir des relations médecin-patient aussi longues et durables.

Même si la demande en matière d'accès aux soins de médecine familiale est croissante et incomblée,[1] ce domaine de pratique unique regroupe plus de 47 000 médecins praticiens au Canada,[2] ce qui souligne son importance dans notre écosystème de soins de santé. En effet, l'augmentation du nombre de médecins de famille par habitant a été directement liée à des avantages mesurables en termes de longévité et de résultats de santé.[3] À ce titre, ce domaine de pratique est incontestablement essentiel au bien-être de la population canadienne.

L'une des caractéristiques déterminantes de la médecine familiale est l'étendue et la portée de sa pratique. C'est la raison pour laquelle les sujets abordés dans le présent numéro reflètent cette réalité. Nous espérons que ce numéro fait écho aux défis et aux avancées actuelles de la médecine familiale. Voici un aperçu de ce à quoi vous pouvez vous attendre dans ce numéro :

PRISE EN CHARGE PAR TÉLÉMÉDECINE DE LA BPCO : UN BREF EXAMEN DES PROGRÈS RÉALISÉS DANS LE TRAITEMENT DES MALADIES CHRONIQUES ET DE LEURS IMPLICATIONS POUR L'ÉDUCATION MÉDICALE

Corrado et Hanycz soulignent l'importance et le potentiel futur de la télémédecine dans la gestion de la BPCO. Grâce aux leçons apprises pendant la pandémie de COVID-19 et aux efforts continus de télémédecine contre la BPCO, les auteurs plaident en faveur de l'introduction formelle des soins de télémédecine dans le programme d'études médicales de premier cycle et de deuxième cycle.

MANIFESTATIONS DERMATOLOGIQUES DE LA COVID-19 : DES PROBLÈMES QUI VONT AU-DELÀ DE LA SURFACE

Dans ce commentaire, Pastukhova plaide en faveur d'un enseignement médical plus diversifié et inclusif des conditions dermatologiques affectant les individus ayant une peau de couleur. Ce sujet est d'actualité étant donné que les conditions dermatologiques liées à la COVID-19 sont de plus en plus courantes alors que les infections par le SRAS-CoV-2 continuent d'être une réalité dans de nombreuses régions du monde. Cet appel à l'action vise directement à approfondir notre compréhension de la dermatologique des peaux de couleur dans la pratique et l'enseignement.

OBSTACLES À LA COMMUNICATION ET DÉFIS À L'ACCÈS AUX SOINS POUR L'AUTISME : MÉDECINE CONVENTIONNELLE VERSUS MÉDECINE ALTERNATIVE

Antoine présente les résultats d'une étude portant sur la dynamique du flux de communication entre les parents/tuteurs d'un enfant autiste et les prestataires de soins de santé alternatifs et/ou conventionnels. À l'aide d'une analyse thématique, cette étude offre un aperçu de l'utilisation de la médecine alternative dans les soins de l'autisme, et identifie les domaines potentiels d'amélioration entre toutes les parties impliquées.

L'ALCOOL ISOPROPYLIQUE COMME TRAITEMENT ANTIÉMÉTIQUE DANS LES SERVICES D'URGENCES : PROTOCOLE D'ÉTUDE POUR UN ESSAI CONTRÔLÉ RANDOMISÉ MULTICENTRIQUE.

Hamelin et ses collègues présentent leur protocole pour un essai contrôlé randomisé prospectif sur l'utilisation de l'alcool isopropylique comme traitement antiémétique. Comme le soulignent des auteurs, les nausées et les vomissements sont fréquents aux urgences et restent difficiles à traiter. Cette étude vise à valider et à examiner les rapports antérieurs, selon lesquels l'alcool isopropylique est un traitement antiémétique efficace avec des effets secondaires minimes dans le contexte des soins d'urgences.

JMUO: PRÉFACE

POSSIBILITÉS D'AMÉLIORATION DE LA QUALITÉ POUR LE SUIVI DES CULTURES D'URINE APRÈS LA SORTIE D'UN SERVICE D'URGENCE DE SOINS TERTIAIRES : UNE ÉTUDE PILOTE

Rajaram et ses collègues présentent les résultats d'une étude pilote examinant et évaluant les processus institutionnels d'assurance qualité dans le contexte des cultures d'urine ordonnées par les services d'urgences. Grâce à l'examen des dossiers médicaux, les auteurs ont identifié des domaines d'amélioration potentielle tout en quantifiant les retards dans les cultures d'urine après la sortie de l'hôpital qui nécessitaient un examen médical.

DISCRIMINATION RACIALE PENDANT LA PANDÉMIE DE COVID-19 ET LA SANTÉ MENTALE DES JEUNES ADULTES : UNE ÉTUDE TRANSVERSALE AUPRÈS D'ÉTUDIANTS UNIVERSITAIRES ORIGINAIRES D'ASIE DE L'EST

Dans une étude transversale, Rodriguez et ses collègues ont étudié l'impact de la xénophobie et de la discrimination raciale pendant la pandémie de COVID-19 sur la santé mentale des étudiants universitaires d'Asie de l'est. À l'aide d'une enquête en ligne, les auteurs ont étudié l'impact de l'efficacité des stratégies d'adaptation et des stades d'identité ethnique/culturelle sur la santé mentale.

UTILISER LA TECHNOLOGIE PORTABLE DE POINT DE VUE COMME OUTIL DANS LES SESSIONS D'ENSEIGNEMENT VIRTUEL POUR COMPLÉTER LA FORMATION EN COMPÉTENCES CLINIQUES : LE POINT DE VUE D'UN ÉTUDIANT EN MÉDECINE

Sheng et ses collègues ont étudié l'utilisation de technologies portables comme outil lors de séances d'enseignement virtuel pour les étudiants en médecine. Étant donné que la COVID-19 a perturbé l'enseignement médical, de nombreuses écoles ayant déplacé leurs programmes précliniques en ligne,[4] les technologies portables peuvent représenter une nouvelle approche pour gérer les obstacles à l'enseignement en personne qui ont résulté de la COVID-19. Cette étude a utilisé la technologie de point de vue lors d'un examen physique abdominal et a recueilli des informations sur l'expérience des étudiants à l'aide de questionnaires.

INTERVENTIONS NON PHARMACOLOGIQUES POUR LE TRAITEMENT DU PHÉNOMÈNE DE RAYNAUD : UNE REVUE SYSTÉMATIQUE

Dans une revue systématique, Mahmood et ses collègues ont analysé et étudié la littérature concernant le phénomène de Raynaud dans le contexte d'interventions non pharmacologiques. Les auteurs ont contextualisé leurs conclusions sur la prévalence et l'étiologie potentielle de cette maladie avant de se pencher en profondeur sur la littérature publiée, de catégoriser les interventions et d'évaluer la qualité des preuves pour chacune d'entre elles. Cette revue systématique a mis en évidence les futurs domaines de recherche sur le phénomène de Raynaud.

Alors que le Canada continue de se diriger vers un contexte post-pandémique, la médecine familiale continue de jouer un rôle de plus en plus important pour tous les Canadiens. Nous sommes convaincus que les praticiens en médecine familiale continueront à relever le défi et à ouvrir la voie à un avenir plus sain.

Au nom de tous les membres du Journal de Médecine de l'Université d'Ottawa, nous vous souhaitons une pratique médicale et de recherche productive, innovante et épanouissante.

Yannick Galipeau
Co-Éditeur en chef (2023-2024)

Telemedicine Management of COPD: A Brief Review of Advancements in Chronic Disease Treatment and Implications for Medical Education

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Date Submitted: July 10, 2022
Date Accepted: November 28, 2022
Date Published: June 30, 2023

DOI: https://doi.org/10.18192/uojm.v13i01.6463

Keywords: *Telemedicine, COPD, Curriculum*

ABSTRACT

Social determinants of health are non-medical, social and economic factors that influence health. The practice of telemedicine enables physicians to virtually connect patients with healthcare resources. Throughout the COVID-19 pandemic, healthcare providers have increasingly utilized telemedicine as a method to provide appropriate care to patients with chronic diseases, including Chronic Obstructive Pulmonary Disease (COPD); a progressive obstructive lung disorder, substantially impacted by social determinants of health including access to healthcare. The successful utilization of telemedicine in the care of patients with chronic diseases, including COPD, highlights its emerging importance in healthcare. However, there is a paucity of published telemedicine curricula by Canadian medical schools, and Canadian student preparedness for virtual healthcare delivery remains unknown, although medical students in other countries report feeling inadequately prepared. Here, we provide a brief review of the utilization of telemedicine in COPD management and advocate for the rapid introduction of a formalized telemedicine curriculum at the undergraduate and postgraduate levels to improve access to care.

RÉSUMÉ

Les déterminants sociaux de la santé sont des facteurs non médicaux, sociaux et économiques qui influencent la santé. La pratique de la télémédecine permet aux médecins de mettre virtuellement les patients en contact avec les ressources de santé. Tout au long de la pandémie de COVID-19, les prestataires de soins de santé ont de plus en plus utilisé la télémédecine comme méthode pour fournir des soins appropriés aux patients atteints de maladies chroniques, notamment la Maladie Pulmonaire Obstructive Chronique (MPOC), un trouble pulmonaire obstructif progressif, fortement influencé par les déterminants sociaux de la santé, y compris l'accès aux soins de santé. L'utilisation réussie de la télémédecine dans les soins aux patients atteints de maladies chroniques, y compris la MPOC, met en évidence son importance émergente dans les soins de santé. Cependant, les écoles de médecine canadiennes ont peu publié de programmes d'études sur la télémédecine, et la préparation des étudiants canadiens à la prestation de soins de santé virtuels reste inconnue, bien que les étudiants en médecine d'autres pays déclarent se sentir mal préparés. Nous présentons ici une brève revue de l'utilisation de la télémédecine dans la gestion de la MPOC et prônons l'introduction rapide d'un programme formel de télémédecine au niveau du premier cycle et du troisième cycle afin d'améliorer l'accès aux soins.

Telemedicine Use in Rural Settings and the Influence of COVID-19

The Canada Health Act aims to provide equal access to care to all Canadians without barriers.[1] Despite this aim, Social Determinants of Health (SDH), including economic stability, education and access to healthcare, continue to act as a barrier against the provision of equitable healthcare services in Canada. Rural-dwelling patients are particularly disadvantaged.[2-4] Decreased proximity to resources and physicians are associated with worse outcomes for patients living rurally.[2-4] The COVID-19 pandemic has further disadvantaged rural living patients by restricting in-person access to an already-limited pool of healthcare services.[5] However, the COVID-19 pandemic accelerated the implementation of alternate healthcare delivery options for urban and rural households, including telemedicine.

Telemedicine is the practice of remote clinical encounters that enable real-time communication between a patient and a healthcare provider.[6] Telehealth is an umbrella term that encompasses the various virtual means to access healthcare services, including telephone and videoconferencing.[6] A 154% increase in videoconferencing as a means to provide telemedicine occurred between January 2020 and the onset of the COVID-19 pandemic in March 2020.[7] Throughout the pandemic, patients and providers have consistently responded favourably to the utilization of telemedicine (Table 1). A 2020 poll of 1800 Canadian residents by the Canadian Medical Association found that Canadian patients reported being satisfied overall (90-92%) when they connected with their physician by video (90%), by phone (91%) or with a virtual health provider (92%), compared to a 98% satisfaction rate for in-person appointments with their physician.[8] 38% of respondents were in favor of virtual appointments as the first point of contact with their physician.[8] In 2021, 94% of Canadian physicians reported using virtual care, and 71% were satisfied with telephone encounters.[9] Collectively, 64% of Canadian physicians are planning to maintain or increase their use of telemedicine within their post-pandemic practice, and patients are satisfied with this implementation.[9] The ubiquitous application in response to COVID-19 and continued utilization has opened the discussion on the role of telemedicine post-pandemic to service patients in urban and rural centers.

Chronic diseases are particularly impacted by reduced access to care.[2-4] and are well-positioned to benefit from improved virtual care platforms. Chronic Obstructive Pulmonary Disease (COPD) serves as an ideal model to highlight the benefit of continued telemedicine use in rural chronic disease management post-pandemic due to elevated exacerbation risk in rural areas and the large number of healthcare resources required for management.[4,12]

COPD as a Model of the Benefits of Telemedicine

COPD is a progressive obstructive lung condition resulting from the interaction between genetic and environmental factors, predominantly tobacco smoking. In 2008, COPD affected more than 700 000 patients in Ontario over the age of 35, accounting for 24% of hospital admissions and 24% of emergency room visits.[10] COPD disproportionately affects patients living in rural areas.[4] SDH, including housing insecurity, food insecurity, and difficulty obtaining transport to appointments are instrumental yet overlooked factors in the management of COPD.[10] Burkes et al., 2018 identified living in a rural area as an independent risk factor for the development of COPD and also increases the likelihood of an acute exacerbation by 70%.[12] Comparative morbidity and mortality figures for patients with COPD in Ontario are elevated in northern and agricultural regions compared to urban areas, mirroring a relative reduction in physician and healthcare resources.[4] 19.4% of patients in Ontario who are admitted for COPD will be re-admitted within thirty days of discharge.[13] The overwhelming number of hospital readmissions in COPD patients, substantial economic burden, reduced access to health care in a rural setting, and the COVID-19 pandemic highlights an opportunity for increased utilization of telemedicine in the management of COPD.

The COVID-19 pandemic has resulted in a monumental shift toward virtual healthcare. Healthcare providers have been encouraged to provide virtual care to outpatients in an outpatient clinical setting to reduce the spread of infection among patients and providers. Despite increased susceptibility to COVID-19 sequelae, hospitalizations due to COPD exacerbations have decreased by 27% to 78% in Spain, Germany, the UK and China during the pandemic compared to pre-pandemic.[14] The precise contributors of hospitalization reduction are unknown but likely involve a combination of pandemic-specific efforts to improve infection control measures (social distancing and hand washing) and increased access to healthcare

via telehealth.[15] Mohammed et al., 2021 demonstrated that 96.6% of primary care providers in southwestern Ontario were offering telemedicine within their clinic, and 66.4% of visits were virtual compared to 6.5% pre-pandemic.[16]

Telemedicine has been shown to be an effective tool against COPD sequelae. A recent systematic review found that the implementation of telemedicine strategies reduces emergency room visits, acute exacerbation-related readmissions and overall mortality.[17] COPD providers have reported that telemedicine can be used to provide high-quality education and anticipatory guidance and provide high-quality care for all aspects of COPD management.[13] Providers have identified increased patient attendance, acceleration of workflows and increased free time as benefits of virtual appointments.[15] Importantly, 91% of providers report that they plan to continue to offer telehealth services post-pandemic.[18] Patients identified an appreciation for the increased clinician-patient engagement and decreased costs (i.e., on-site patient parking costs, fuel costs) that occur with telehealth. Further utilization of telemedicine by COPD providers and patients would help to minimize COPD exacerbations in rural populations and therefore reduce hospitalizations and associated economic burdens. However, access to high-quality internet is required for a seamless telemedicine encounter and is known to differ based on age, sex, ethnicity, education, and income.[19] This poses a potential barrier in COPD management that must be addressed in a future medical system that relies on virtual appointments.

Current short- and long-term Canadian COPD guidelines include a combination of education, pharmacotherapy and rehabilitation.[20] Bronchodilators such as beta2-agonists and antimuscarinics are utilized to reduce the frequency and severity of symptoms, reduce exacerbations and improve exercise tolerance.[20] However, incorrect inhaler technique may diminish their effectiveness in COPD patients. Additional long-term management strategies include pneumococcal and influenza vaccinations, pulmonary rehabilitation and home oxygen therapy when indicated.[20] Decreased proximity to medical care in rural settings limits the utility of pulmonary rehabilitation and access to medication.[2-4] Telemedicine provides an alternate avenue towards ensuring optimal patient care in rural settings by enabling high-quality COPD management from a distance. A recent clinical trial comparing conventional in-person follow-up to telemedicine follow-up found that there was no significant difference in time until the first exacerbation and in the number of exacerbations between the two groups.[21] Telemedicine implementation therefore enables healthcare providers to provide consistent patient education, symptom assessment, the opportunity to modify treatment accordingly, and access to specialists distant from rural centers.

The success of currently recommended COPD treatment protocols is dependent on patients' ability to access healthcare and the financial resources to access therapy. Patients are known to struggle with self-management following diagnosis secondary to SDHs, leading to increased re-admissions.[10] This is particularly true in rural areas, where access to a holistic COPD management team is difficult. Telemedicine is a sustainable solution to mitigate poor outcomes experienced by patients with decreased access to healthcare. Patients and providers have both reported high rates of satisfaction with telemedicine, and providers have expressed interest in continuing virtual consultations post-pandemic. Additionally, there is evidence to suggest that COPD management via virtual means has similar outcomes as its in-person counterpart. For example, the effectiveness of inhaler education among asthma and COPD patients was found to be similar irrespective of delivery method (in-person or virtually).[22] The emergence of telehealth to provide high-quality, sustainable medical management to patients with COPD will continue to be an essential tool in the management of rural-based patients with chronic diseases.

Telemedicine Instruction in Undergraduate Medical Education

As virtual care modalities become increasingly implemented into modern healthcare, it is essential that medical students are trained to leverage such technology effectively.[23] Undergraduate medical education represents an invaluable window of opportunity to lay the foundations of virtual care delivery for future physicians.[23] To date, only seven peer-reviewed studies have been published on undergraduate telemedicine curricula, including four in the USA, two in Australia and one in Switzerland.[24] More recently, the University of Ottawa has published a list of formal learning objectives to be implemented into its growing telemedicine curriculum.[25] There remains, however, a scarcity of peer-reviewed studies of telemedicine curricula in Canadian medical schools. Comparatively,

The Society of Teachers of Family Medicine (STFM) in the USA formed a task force at the onset of the COVID-19 pandemic to formally develop a national telemedicine program for family medicine residents and practitioners.[26] Medical students report feeling unprepared to effectively employ telemedicine upon graduation,[27] and 88% of medical students in one study agreed that telemedicine is an important educational tool that would be highly relevant in their future practice.[28] It is of vital importance that telemedicine education be formalized in order to properly meet the post-pandemic preferences of the Canadian population. Curricula coordinators can refer to previously published telemedicine programs.[24, 25] to guide initial curriculum development.

Medical trainee programs may leverage existing practice and assessment methods to implement core concepts of telemedicine. Many physicians have and will continue to adopt telemedicine into their practice. Trainees must be encouraged to practice telemedicine while working with preceptors who can provide foundational skills for a future career that may utilize telehealth technology. Medical education programs may distribute existing telemedicine videos, journal articles and supplementary resources to their trainees or develop their learning material tailored to their curriculum. Additionally, Objective Structured Clinical Examinations (OSCEs), which have been used by medical schools worldwide for decades to assess clinical skills, can be adapted to formally evaluate a trainee's performance during a standardized telemedicine encounter.

Table 1. Telemedicine perceptions among Canadian physicians and patients during the COVID-19 pandemic. Adapted from references.[8,9]

% of patients who reported being satisfied overall with a phone appointment with their doctor	91
% of patients in favor of having first appointment with physician in virtual setting (phone, video, email, text) rather than an in-person appointment	38
% of physicians who report use of virtual care in their practice	94
% of physicians who reported being satisfied overall with telephone appointments	71

Conclusion

The COVID-19 pandemic has increased the availability and recognition of telemedicine as an option to provide high-quality medical care. Widespread implementation of telehealth modalities in addition to in-person visits seeks to minimize healthcare disparities between rural and urban-based patients. Reduced disparities in access to care has the potential to improve patient outcomes in long-term chronic disease management. Medical schools and residency programs have an obligation to integrate telemedicine into their curricula in an effort to better prepare trainees for the future of healthcare.

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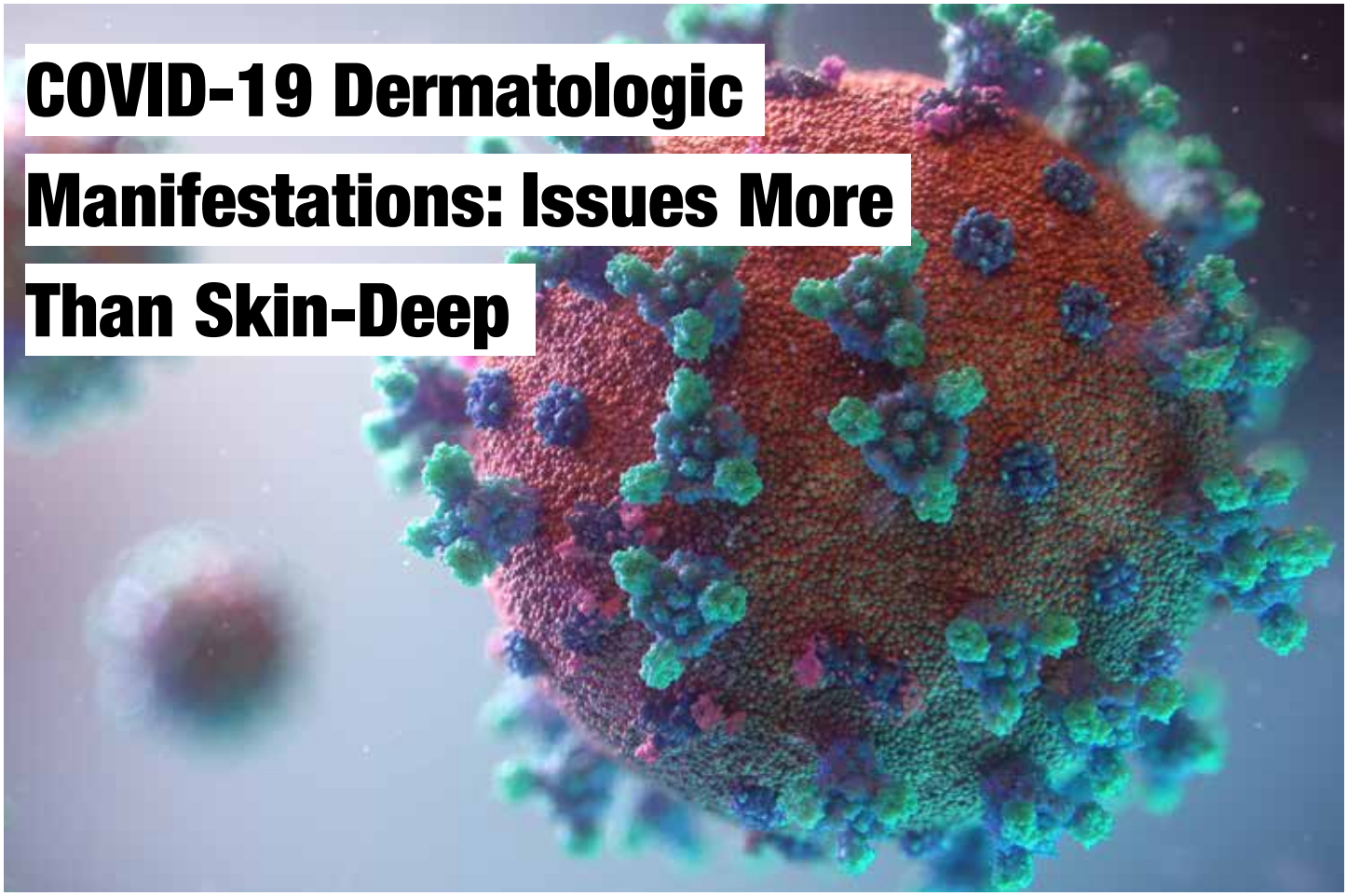
COVID-19 Dermatologic Manifestations: Issues More Than Skin-Deep



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Date Submitted: March 27, 2022
Date Accepted: May 19, 2022
Date Published: July 6, 2023

DOI: https://doi.org/10.18192/uojm.v13i01.6269

Keywords: *COVID-19, cutaneous manifestations, skin of colour, dermatology*

ABSTRACT

Dermatologic manifestations of COVID-19 have become increasingly more common. These dermatoses can either precede, accompany, or follow respiratory symptoms of COVID-19, and some may even correlate with the severity of the disease. Although COVID-19-related skin changes are relatively rare, there is an even greater lack of such data in individuals with skin of colour. While research into the pathophysiology of this phenomenon is in its nascency, it is paramount to recognize the need for diversification, especially considering the racial disparities of COVID-19. The present discussion is a call-to-action to improve diversity in our teaching of dermatologic conditions and advance our understanding of skin of colour dermatology in the medical profession.

RÉSUMÉ

Les manifestations dermatologiques du COVID-19 sont de plus en plus fréquentes. Ces dermatoses peuvent précéder, accompagner ou suivre les symptômes respiratoires du COVID-19, et certaines peuvent même être en corrélation avec la gravité de la maladie. Bien que les modifications cutanées liées au COVID-19 soient relativement rares, on manque encore plus de données à ce sujet chez les personnes ayant une peau de couleur. Alors que la recherche sur la physiopathologie de ce phénomène n'en est qu'à ses débuts, il est primordial de reconnaître la nécessité d'une diversification, surtout si l'on considère les disparités raciales de la maladie de COVID-19. La présente discussion est un appel à l'action pour améliorer la diversité dans notre enseignement des affections dermatologiques et faire progresser notre compréhension de la dermatologie de la peau de couleur au sein de la profession médicale.

The coronavirus disease 2019 (COVID-19) global pandemic continues to leave a devastating footprint on our society. According to the most recent epidemiological report from the World Health Organization, over 468 million cases have been reported worldwide, with over 6 million deaths.[1] The most common clinical manifestations of COVID-19 are fever, cough, chills, and dyspnea, however, there is an increasing emergence of documented cutaneous manifestations that may precede the onset of respiratory symptoms.[2,3] Unfortunately, the publications citing skin manifestations related to COVID-19 are almost exclusively described in patients with lighter skin, despite evidence they are also present in skin of colour (SOC).[4,5] This not only potentially impacts early recognition and diagnosis of COVID-19 in patients with SOC but also casts light on a deeper issue of the under-representation of SOC in medicine. Importantly Black, Hispanic, Latino, Native American, Indigenous Peoples, Asian, and Pacific Islander communities have been shown to be at a disproportionately increased risk of morbidity and mortality due to COVID-19.[6–10] Public policy should address the racial disparities in health outcomes precipitated by the COVID-19 pandemic and improve the diverse representation of dermatologic manifestations in medical literature, training, and care provision.

A systematic review demonstrated that the overall frequency of dermatologic manifestations in COVID-19 infections was 5.95%, though this finding did not examine data by race.[2] The most common skin lesions reported were maculopapular rashes, vesicular lesions, urticaria-like lesions, vascular lesions, and chilblain-like lesions, yet there is an absence of classification of these lesions related to race and ethnicity.[2,11–13] The exact relationship between COVID-19 cutaneous manifestations and disease severity has yet to be elucidated; however, chilblain-like and vascular lesions have been described as opposite ends of a spectrum of increasing disease severity.[2] Additionally, urticaria-like lesions co-occurred with common, extracutaneous COVID-19 symptoms in 47% of patients and the authors postulated urticaria-like lesions to be potentially useful in raising the level of suspicion towards COVID-19 as opposed to other respiratory illnesses.[2] Moreover, patients with chilblain-like lesions were most likely to be otherwise asymptomatic at presentation. These findings present a challenge for patients with darker skin as it is an established fact that dermatoses vary morphologically between different racial groups.[14,15] As such, without more data, it is unclear if differences also exist in the appearance of COVID-19 dermatoses in SOC, as well as whether they differentially impact clinical prognosis. Provided that COVID-19 variants can be highly virulent, transmissible, and have a long asymptomatic latency period,[16] it is imperative to expand our knowledge of the various physical findings in the COVID-19 clinical gestalt. Particularly, such knowledge would potentially allow for the identification of asymptomatic or mildly symptomatic patients and guide care appropriately. Importantly, in communities of people with SOC, awareness about COVID-19 dermatoses could lead to fewer diagnostic delays and improve outcomes through earlier interventions.[17] Additionally, patients with SOC are disproportionally affected by post-inflammatory hyperpigmentation (PIH) which can follow active dermatoses.[18] PIH can persist for many years and has been shown to have a significant impact on patients' quality of life, often requiring nuanced and challenging treatment.[19] Thus, recognition of COVID-19 dermatoses in patients with SOC could also aid in the earlier treatment of and/or prevention of associated PIH. Though reporting bias could explain the scarcity of cases, it is also possible that dermatologic manifestations of COVID-19 may be uncommon in SOC.[20,21] Nevertheless, in addition to encouraging the scientific community to report on such data, it would also be beneficial to create international photo registries of SOC dermatoses that clinicians can virtually access, as suggested by Akuffo-Addo et al.[17] An example of such an initiative is Project IMPACT by VisualDx, which is an international medical resource platform that includes the largest online library of SOC pathology to date.[22,23] Efforts should be made to further investigate COVID-19-related dermatologic manifestations in SOC to potentially provide an additional way for healthcare practitioners to care for under-represented populations through earlier recognition and proper treatment of such patients.

Unfamiliarity with the presentation of dermatologic concerns in SOC has detrimental consequences that long predated the COVID-19 pandemic. Dawes et al. demonstrated significantly lower survival of Black patients compared to white patients diagnosed with malignant melanoma.[24] Black patients have also been shown to present at later stages of skin cancer and have significantly longer time-to-treatment compared to white patients.[25] In fact, disparities for individuals with SOC have been described across many dermatologic outcomes and in research.[26] The reasons for this are multifactorial, but awareness of and education about SOC on behalf of medical professionals were cited as contributing factors. Gaps in the literature

impact the awareness and understanding of dermatoses in SOC as well as limit the applicability of therapies, preventative measures, and clinical trials. For example, studies show that skin cancer prevention and sunscreen use have significantly less attention in Black and Hispanic communities.[27] As medical professionals, it is prudent that we emphasize the importance of sun safety in individuals of all skin colours. Importantly, medical professionals must recognize the unique attributes of SOC and presentation of disorders thereof to improve patient outcomes. In fact, physicians' familiarity with SOC has been shown to favourably impact patient-doctor relationships. One study demonstrated that Black patients ranked knowledge of disorders of Black skin and hair as one of the fundamental factors to the rapport with their dermatologist.[28] The same study also assessed patients' satisfaction using a 5-point Likert scale and found that Black patients (n=19) treated by dermatologists in a SOC clinic were significantly more satisfied with cultural sensitivity to Black skin (mean score 4.43, p=0.01) and knowledge of Black skin (mean score 4.36, p=0.02) compared to those treated in a non-SOC clinic (mean scores 2.96 and 2.82, respectively). Healthcare providers' knowledge of SOC and its dermatoses not only improves patient outcomes, but fosters culturally competent, patient-centered relationships.

Awareness and knowledge surrounding SOC are predicated on the proper training of medical professionals. In one study, 47% of U.S. dermatologists felt that insufficient training and exposure were provided in diagnosing patients with SOC.[26] A 2020 survey of U.S. dermatology residents echoed these findings.[29] At their core, medical training programs and educational resources should equip their students with the ability to correctly recognize, diagnose, and manage skin diseases in all phototypes. Studies that examined images of different skin phototypes in dermatology textbooks concluded that there is a limited depiction of 'darker skin,' which the authors defined as Fitzpatrick V-VI.[30,31] The largest proportion of images portraying darker skin in textbooks was found to be 22-32%.[31] Additionally, textbooks designed for dermatology training were more likely to show images of darker skin than textbooks believed to be read by generalists.[30] In other words, primary care physicians may have limited exposure to SOC in their learning and thus be ill-equipped to diagnose skin concerns. Importantly, this type of teaching must be addressed at the foundation of medical education – medical school. When asked to diagnose dermatoses presented on images, medical students showed the greatest gap in recognizing the following skin diseases between Fitzpatrick IV-VI and Fitzpatrick I-III phototypes, respectively: squamous cell carcinoma (14.9% versus 45.6%; p<0.0001), urticaria (57.5% versus 82.2%; p=0.0003), and atopic dermatitis (74.4% versus 86.2%; p=0.0495).[32] The authors theorized these findings to largely be due to reliance on dark pigment and/or erythema as diagnostic features, which may not be pertinent to Fitzpatrick IV-VI phototypes.[33] Medical schools and residency programs must construct curricula that integrate dermatology of darker skin into their teaching. This should not be limited to modules dedicated to unique features of SOC but incorporated into all teaching that presents skin to students and residents. A 2019 in-depth review of dermatology training and practice prepared by the Royal College of Physicians and Surgeons of Canada highlighted the commitment to revise the discipline's standards to address the needs of diverse populations.[34] Additionally, national societies of dermatologists, such as the Skin of Colour Society in the United States, have been created to promote awareness of SOC dermatology through education of healthcare providers, the general public as well as through supporting SOC research.[35] Ogunyemi and Miller-Monthrope proposed the creation of a national society of dermatologists analogous to the Skin of Colour Society as a future possibility in Canada.[36]

Approximately 32% of Canadians will belong to non-white ethnic groups by the year 2031.[37] The practice of medicine that acknowledges, respects, and acts on commitments to provide equitable care to patients with SOC should be the norm rather than a theoretical ideal. As we continue to learn more about the pathophysiology of COVID-19, dermatologic manifestations should not be omitted from discussions surrounding its recognition and diagnosis. Importantly, knowledge surrounding COVID-19 dermatologic manifestations in SOC would potentially aid in earlier diagnosis, treatment, and management of complications in populations already disproportionately impacted by this pandemic. Above all, the scarcity of SOC teaching in our training will continue to exacerbate existing racial disparities in the field of medicine. We must prioritize a culturally competent system and education of future healthcare professionals to regain the trust of these communities.

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Communication Barriers and Challenges for Accessing Autism Care: Conventional Versus Alternative Medicine

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Date Submitted: June 28, 2022
Date Accepted: December 13, 2022
Date Published: July 19, 2024

DOI: https://doi.org//10.18192/uojm.v13i1.6430

Keywords: *Autism spectrum disorder, autism care management, conventional medicine, alternative medicine, parent-provider communication*

ABSTRACT

Background: Despite the widespread use of complementary and alternative medicine (CAM) for autistic children, little is known about the communication flow between the different parties involved in the care (i.e., parents/caregivers, conventional providers, alternative practitioners). This study aimed to describe how communication occurs through the first year of care to identify challenges and potential barriers to communication that may affect the care of autistic children.

Methods: From an ecological perspective, we collected qualitative data through 12 semi-structured interviews with six parents/caregivers, three conventional providers (family doctor, neurodevelopmental pediatrician, psychologist), and three alternative practitioners (naturopath, occupational therapist, speech and language pathologist) operating in Ottawa, Canada. The data was interpreted using thematic analysis.

Results: Findings revealed that parents and caregivers are the only links between the health professionals of both streams. The communication between parents/caregivers and conventional providers faces a perceived lack of knowledge of these professionals relating to CAM, a lack of care integration, flexibility, and time constraints. In alternative care settings, care integration and time constraints are an issue. From the five contexts examined, only the organizational and interpersonal contexts influence communication flow within the system.

Conclusions: The increasing interest in alternative medicine is forcing changes in the healthcare system. Within the identified themes in the current study, the necessity for communication between all parties involved in the care of autistic children is evident. More ASD and CAM-related training for providers and openings for information-sharing between the two streams would support effective parent/caregiver-care provider communication. These findings contribute to a better understanding of the role of communication in the care management of autism, which has implications for effective autism care.

RÉSUMÉ

Contexte: Malgré l'utilisation répandue des médecines complémentaires et alternatives (MCA) pour les enfants autistes, on sait peu de choses sur le flux de communication entre les différentes parties impliquées dans les soins (c.-à-d. les parents/soignants, les fournisseurs conventionnels, les praticiens alternatifs). Cette étude visait à décrire la façon dont la communication se déroule au cours de la première année de soins afin d'identifier les défis et les barrières potentielles à la communication qui peuvent affecter les soins aux enfants autistes.

Méthodes: Dans une perspective écologique, nous avons recueilli des données qualitatives par le biais de 12 entretiens semi-structurés avec six parents/soignants, trois prestataires conventionnels (médecin de famille, pédiatre spécialisé dans le développement neurologique, psychologue) et trois praticiens alternatifs (naturopathe, ergothérapeute, orthophoniste) exerçant à Ottawa, au Canada. Les données ont été interprétées à l'aide d'une analyse thématique.

Résultats: Les résultats ont révélé que les parents et les soignants sont les seuls liens entre les professionnels de la santé des deux courants. La communication entre les parents/soignants et les prestataires conventionnels se heurte à la perception d'un manque de connaissances de ces professionnels en matière de MCA, à un manque d'intégration des soins, de flexibilité et de contraintes de temps. Dans les contextes de soins alternatifs, l'intégration des soins et les contraintes de temps posent un problème. Parmi les cinq contextes examinés, seuls les contextes organisationnel et interpersonnel influencent le flux de communication au sein du système.

Conclusions: L'intérêt croissant pour les médecines alternatives impose des changements dans le système de soins de santé. Parmi les thèmes identifiés dans la présente étude, la nécessité d'une communication entre toutes les parties impliquées dans les soins aux enfants autistes est évidente. Une formation plus poussée des prestataires en matière de TSA et de MCA et des possibilités d'échange d'informations entre les deux courants favoriseraient une communication efficace entre les parents, les soignants et les prestataires de soins. Ces résultats contribuent à une meilleure compréhension du rôle de la communication dans la gestion des soins pour l'autisme, ce qui a des implications pour une prise en charge efficace de l'autisme.

INTRODUCTION

There is no such thing as a typical autism disorder.[1] Autistic children do not require the same care, and interventions do not yield the same results.[2] Autism care requires a multidisciplinary team[3] comprising parents and a range of health professionals. In Ontario, when a diagnosis is posed by qualified professionals (i.e., family physicians, pediatricians, developmental pediatricians, psychiatrists, psychologists, psychological associates, and nurse practitioners), it is usually followed by planning for the implementation of a care plan. Conventional medicine, considered "mainstream" medicine, supports several therapies, including interventions such as developmental programs, speech-language therapy, occupational therapy, physical therapy, etc.). This type of medicine is generally provided in hospitals and specialty or primary care practices. It is sometimes also referred to as "evidence-based."[4]

Although conventional medicine is the dominant healthcare delivery system, it coexists with many other approaches in the care of autistic children.[5] In cases of autism, complementary and alternative medicine (CAM) is often used to supplement or replace conventional therapies. CAM includes all such practices and ideas self-defined by their users as preventing or treating illness or promoting health and well-being.[6] Current literature notes a high usage rate of alternative treatments in autism[7,8] and a lack of information sharing between parents and conventional providers.[9] Regardless of the approach, autism care requires coordination between a number of health professionals,[10] making communication in this context an area of interest. Communication is key to the delivery of quality care.[11-13] Nevertheless, the literature relating to the communication flow between parents/caregivers and professionals of conventional and alternative streams is relatively poor.

According to Rickel and Wise,[14] the key to the proper functioning of a system is effective communication between its various elements. Then, the current study aims to gather information to describe how communication occurs between the parties involved in the care of autistic children within the healthcare system in Ottawa during the first year of care to identify challenges and potential barriers to communication.

The Current Study

Autism is a complex developmental disorder that occurs very early in life, as early as 18 months.[15] It lasts a lifetime.[16] The presence and intensity of the disorder may change over time and vary from one individual to another. Most often, parents are the ones who express the first concerns about their child's development[17] and consult a healthcare professional. However, because autism is not a disease, it is not cured by medical interventions and medications.[18] Available interventions/treatments are specific to the stream through which they are offered. Nevertheless, experts

agree on the importance of early intervention, which may reduce the intensity of the syndrome or minimize its effects on the child's development.[19]

Conventional medicine is practiced by medical degree holders and allied health professionals. The recommendations focus on behavioural therapies to modify specific behaviours in affected children. These include special education programs based in Applied Behavioural Analysis (ABA) or Intensive Behavioural Intervention (IBI), which are widely accepted.[2] Providers may add occupational therapy, speech therapy, or physical therapy to the care plan which are generally funded through specialized centres.[20] Medication is only discussed when co-occurring developmental, mental, and physical health conditions are present.

A separate stream, known under different designations (e.g., natural, alternative, unconventional, traditional, parallel, or complementary medicine), advocates using vitamins and normal body constituents in large quantities as the main treatment.[21] The treatments used for individuals include diets (e.g., gluten-free diet), dietary supplements (e.g., vitamins), mind-body medicine (e.g., hypnosis, shamanism), homeopathic remedies, acupuncture, and animal-assisted therapy (e.g., dolphin therapy, therapeutic horseback riding).[22] Although the Canadian healthcare system is an integrated system that allows for the addition of several disciplines considered complementary to conventional healthcare services, alternative medicine for autism is not one of them.

Alternative treatments are not scientifically proven and pose safety concerns due to potentially dangerous side effects.[7] However, they are used to supplement the care of a high number of autistic children.[8] Conventional therapies may be put on hold or discontinued in favor of alternative treatments.[10] In some instances, parents may follow alternative recommendations without consultation with the conventional healthcare professional. In this context, we question the communication dynamic between parents/caregivers, conventional providers, and alternative practitioners to identify potential challenges and barriers to communication that may impact the care of autistic children.

In general, communication is the act of communicating with someone, relating to others through language; it describes the interpersonal nature of human experience.[23] For us, communication represents dialogue, discussion, rapport, exchange, collaboration, knowledge-sharing, information-sharing, and any other that research participants identified as communication in their interactions.

Theoretical Framework

A system refers to a set of elements standing in interrelation among themselves and with the environment.[24] According to the general theory of systems, a system can establish equilibrium if it has the capacity to regulate itself after a disturbance.[25] The interest in alternative treatments and their use opens the door to a stream that operates outside the norms of the traditional healthcare system. Which not only forces change in conventional settings but may impact the entirety of the system.

The theoretical framework refers to the ecological model of communication developed by Street, an approach that examines the interrelation between organisms and their environment. An ecological perspective examines the interaction between health professionals and patients in different social contexts and their influence on communication.[26] Street identified five contexts: interpersonal, organizational, media, politico-legal, and cultural.

The interpersonal context looks at the patterns of provider-patient communication relating to the attributes of the patient (e.g., education, age, health status), the provider (gender, medical specialty), and their relationship (rapport, trust). In addition, it examines relationships between providers' and patients' communicative actions and the various outcomes (mostly patient-focused) resulting from the consultation (e.g., satisfaction with care, commitment to treatment, health improvement).[26] The organizational context refers to the healthcare environment. The size of the facility, the types of service offered, location, clientele, healthcare standards, etc. In the media context, the medium examined under the ecological model is the Internet for its potential in significantly changing the way healthcare providers and patients interact with each other. The politico-legal context encompasses the legal and juridical actions relevant to delivering medical care. The cultural context involves any situation where attitudes about ethnicity and stereotypes held by healthcare providers and patients may impact communication.[26]

For Street, communication is central to the delivery of healthcare.[26] However, the environment in which it

occurs can be disruptive. To that end, our study of the communication flow amidst the disturbances created by the use of two different streams in the care of autistic children aims to shed light on the challenges and potential barriers to communication within the system.

METHODS

In this study, we aim to describe how communication occurs between the parties involved in the care of autistic children within the healthcare system in Ottawa during the first year of care to identify challenges and potential barriers to communication. Considering that individuals experience situations according to their position, expectations, needs, and reading, we opted for triangulation of sources for this study[27] (Figure 1).

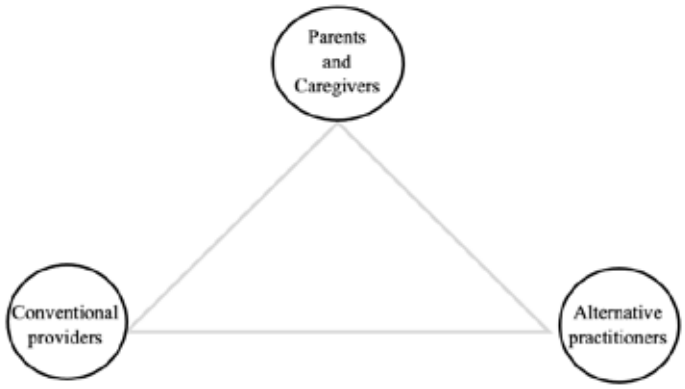

Figure 1. Triangulation of sources (parents and caregivers, conventional providers, alternative practitioners) - the actors involved in children autism care in Ottawa.

Data source triangulation involves collecting "data from different types of people, including individuals, groups, families, and communities, to gain multiple perspectives."[28] The use of different sources allowed for a sample of each group of actors involved in the care of an autistic child. It facilitated an analysis within each context and in different settings with all parties involved. Each end of the triangle represents a category of participants (parents/caregivers, conventional medicine providers, alternative medicine practitioners). We placed the parents/caregivers at the top of the triangle because they are the gatekeepers for their child's treatment.[29] Various studies highlight the importance of parents/caregivers' role in the care of children.[30-32]

From an ecological perspective, we collected qualitative data through semi-structured interviews with participants from each source of our triangulation (interview guides in Appendix). The data collected were analyzed through thematic analysis.[33] Each side of the triangle represented the communication between two parties involved in the care. Thus, we examined each side per each of the five contexts of the ecological model to extract commonly recurring themes from the meanings given to their experiences by the participants.

Participants

The Ministry of Children and Youth Services (MCYS) provides funding for the following five components: autism treatment, family support services including training, transition and support services, school support program, and respite services. Most of these services are accessible through the Children's Hospital of Eastern Ontario (CHEO) and its Children Treatment Centre (CTC). Therefore, through purposive sampling, we ensured the participation of healthcare providers and parents/caregivers through these services and selected alternative practitioners operating in Ottawa.

Twelve participants gave consent to this study. Parents/caregivers of an autistic child using conventional medicine only (n = 3), parents/caregivers of an autistic child using conventional and alternative medicine or alternative medicine (n = 3), conventional medicine providers (n = 3), alternative medicine practitioners (n = 3).

Table 1. Participant Information

PARTICIPANT	GENDER	ROLE
PC01	F	Mother
PC02	F	Mother
PC03	M	Father
PCA01	F	Mother
PCA02	F	Aunt
PCA03	F	Mother
MC01	F	Family doctor
MC02	M	Developmental doctor
MC03	M	Psychologist
IA01	M	Speech pathologist
IA02	M	Naturopath
IA03	F	Occupational therapist

Recruitment

We recruited parents/caregivers through contacts at the Faculty of Health Sciences at the University of Ottawa, word of mouth, and advertisements on social media. Research information sheets were provided along with a consent form. Additional information was provided by phone or in-person when required.

Inclusion criteria: All participants were to consent to participate in the study. Parents/caregivers had to be Ottawa residents using services in the region, conventional or alternative medicine only or a combination of both streams. All parents were at least six months post-diagnosis because it usually takes that long before a follow-up appointment if the child presents no medical concerns. In addition, this allowed time for a care plan to be put in place in conventional settings and for parents/caregivers to possibly gather information, which could lead to using alternative treatments. Conventional and alternative care providers had their practices in the Ottawa region and had/have had at least one autistic child as a patient.

Recruitment Difficulties

For conventional care providers, our goal was to secure the participation of CHEO's CTC, which offers government-funded autism services, including diagnosis and care management. Though confidentiality was assured, the Centre refused formal participation in the study due to the controversies surrounding alternative medicine. However, we secured the participation of at least one doctor from the Centre. In addition, talking about alternative medicine represented an issue for conventional medicine providers who indicated not knowing enough on the subject to participate in the research, although they felt that the investigation was warranted. Several parents/caregivers declined to participate because they felt too emotional to discuss their child's diagnosis. These refusals considerably reduced the number of confirmed participants in the study. However, we were able to obtain an equal number of participants per group.

Procedures

Participant categories were coded to ensure confidentiality (Table 2). The interviews with the care providers lasted 20-30 minutes.

Table 2. Participant Coding

TYPE	ROLE	CODE
Source 1	Parents or caregivers of a child with autism using conventional medicine only	PC
	Parents or caregivers of a child with autism using conventional and alternative medicine or alternative medicine only	PCA
Source 2	Conventional providers in the Ottawa area who have or have had at least one autistic child with autism as a patient	MC
Source 3	Alternative practitioners in the Ottawa region who work or have worked with at least one autistic child	IA

We obtained ethical approval from the University of Ottawa Office of Research Ethics and Integrity (IRB 06-10-23). The interviews were scheduled based on participants' availability. The twelve participants completed individual interviews conducted by the researcher in French or English, depending on the participant's preferred language. The confidential nature of the face-to-face interviews facilitated the process and made it easier to register the participants' opinions and descriptions of their experiences. Interviews were recorded on an iPhone and confidentially transcribed for analysis.

Materials

Semi-structured interview guides specific to each group of participants were developed in both French and English. The questions were designed to allow flexibility for the researcher to follow up on participants' answers and prompt for more in-depth information, when required, during the semi-structured interview process. The verification questions were formulated to address the communication process specifically; thus, they were only used when more information or clarifications was required (n = 12).

For the parents/caregivers, sixteen questions and two verification questions were used, as needed, to explore the communication with conventional or alternative medicine providers, between conventional and alternative medicine providers, and the general communication process through the system.

For providers, eighteen questions and two verification questions were used, as needed, to explore the communication with parents/caregivers and with other care providers conventional or alternative involved in the care of their autistic patients.

Analyses

This study required a good understanding of the situation in order to describe and interpret communication practices between parents/caregivers, conventional providers, and alternative practitioners. We analyzed the data collected from the interviews according to the six steps of thematic analysis put forth by Braun and Clarke (2006): (1) Becoming familiar with the data, (2) generating coding categories, (3) generating themes, (4) reviewing themes, (5) defining and naming themes, and (6) locating exemplars. This process allowed to generate themes from the collected data and interpret patterns. Some words or concepts were used during the coding phase because they were repeated during an interview or in several interviews. The frequency of occurrences was considered, but no themes were suppressed, even if they only appeared once in the participant's discourse.

Table 3. Themes emergence by participant category

		THEMES			
		Provider knowl-dge	Care integra-tion	Flexible care	Time con-straints
Source 1	PC01	x	x		x
	PC02	x			x
	PC03	x	x	x	x
	PCAO1	x	x		x
	PCA02	x	x	x	x
	PCA03	x	x	x	x
Source 2	MC01	x	x	x	x
	MC02	x	x	x	x
	MC03	x	x	x	x
Source 3	IA01	x	x	x	x
	IA02	x	x	x	x
	IAO3	x	x	x	x

Street's ecological model guided the analysis providing keys allowing us to place the relationships between the different actors in a larger context, relational, organizational, and societal, guiding through the various possible contexts in which there can be communication and the influence of these contexts on the communication.

RESULTS

The qualitative data analysis led to the emergence of four themes: provider knowledge, care integration, flexible care, and time constraints. These themes symbolize the participant's discourse as well as our interpretation.

Table 4. Themes emergence in participant discourse

Themes	At least one appearance under each source of our triangulation
Provider knowledge	*"Physicians are not knowledgeable when it comes to alternative practices." (PCA01)* *"I am not well-versed in alternative practices, and I do not keep up-to-date with advances in that area," "all we know is from parents; we must rely on their reports." (MC01)* *"Doctors couldn't do anything with the information because they are very busy." (IA02)*
Care integration	*"I find that alternative practitioners are willing to share, and they do share with each other […] but, doctors are kept out of it." (PCA03)* *"I have to admit there is some overlap between the two approaches." (MC03)* *"I never contacted a doctor in all my years of service." (IA01)*
Flexible care	*"I feel pushed aside because there is nothing they can do for my son." (PC01)* *"Any parent may be somewhat apprehensive about disclosing certain alternative treatments if they think the doctor is not going to approve." (MC01)* *"The College has established a way to talk with parents." (IA01)*
Time constraints	*"Communication is limited. They focus on their work with my child, but alternative practitioners take the time to answer questions and make suggestions." (PCA02)* *"I don't have time to do everything during a visit, especially since visits are now shorter, there is not enough time." (MC02)* *"My workload is considerable because there are very few Speech-language pathologists, we want to spend more time on the intervention, but there is little time left to talk to the parents." (IA01)*

In this section, the themes are described, supported by excerpts taken directly from the interviews.

Themes

The themes were found under each source of our triangulation. At least one appearance under each of the three categories of participants was required.

Theme 1 – Provider knowledge

Parents/caregivers perceive their healthcare provider's silence relating to alternative medicine as a lack of knowledge on their part. They *"do not make recommendations about alternative medicine." "Physicians are not knowledgeable when it comes to alternative practices." "The doctor doesn't really understand what's going on, he's always trying to prescribe drugs, trying to make life easier for me and my husband."* Moreover, they do not feel able to speak freely with their child's doctor, *"there is almost a taboo when it comes to questioning about alternative medicine."* Which causes them to worry about what they don't know, *"I didn't want the doctor to have a monopoly and not give me all the information."*

Conventional care providers agree that they lack knowledge about alternative medicine. *"I am not well-versed in alternative practices, and I do not keep up-to-date with advances in that area," "all we know is from parents; we must rely on their reports."* In addition, *"there is no magic cure; if there were a form of healing, we would be using it."*

While knowledge is not a concern for parents/caregivers in alternative care settings, alternative providers indicate that families should discuss alternative treatments with their doctors. However, *"it would depend on his or her level of knowledge about it."* Although they feel that regardless, *"they couldn't do anything with the information because they are very busy."* It would also depend *"on the trust relationship established." "Knowing that the doctor is open and would be willing to discuss it is a good thing; it helps to build trust."*

Theme 2 – Care integration

Overall, participants agree on a lack of continuity in the system. Health information is not shared with all professionals involved in the care. Conventional providers do not share communications with alternative practitioners and vice versa. Parents/caregivers indicate that *"alternative practitioners are willing to share, and they share within their stream, but the doctor is kept out of it."* They report being able to share with alternative practitioners but often choose not to. The same occurs with conventional providers because parents and caregivers say: *"I feel rushed," "it is hard to focus with my son in the room," "there is not enough time."*

Conventional care providers admit that they do not initiate talks about alternative treatments with parents/caregivers. The financial implications play a significant role *"I don't want parents to have to bear this burden or be overwhelmed by the cost of such treatment if it is not realistic for them."* It is *"a very heavy financial burden on families. Everything is paid for out of their pocket and can be very expensive."* However, they are open to information-sharing, *"I would like to receive letters from these practitioners."* Some alternative processes are used in conventional settings. *"I have to admit there is some overlap between the two approaches … we prescribe OMEGA 3 fatty acids, … massage, multivitamins, and B-complex vitamins for our autistic patients."* Nevertheless, there is no provision for information-sharing between healthcare professionals of both streams, *"we would not be paid for the time allocated to exchange with alternative practitioners."*

Alternative practitioners confirm no contact with conventional providers: *"I never contacted a doctor in all my years of service."*

Theme 3 – Flexible care

Health professionals of both streams admit to a lack of flexibility in their practices. They must abide by the policies guiding their practice. Parents/caregivers expressed their frustration about appointment scheduling. *"The routine appointments are scheduled every six months or more."* This approach does not help, *"I feel pushed aside because there is nothing they can do for my son."* Professional referrals are also an issue. In conventional settings, referrals are limited to specific professionals. Alternative medicine choice is mainly done through *"auto-reference."* Alternative practitioners indicate that *"the College of Professionals has established a way to talk with parents, … we cannot write recommendations," "we are not allowed to write to conventional physicians."* Beyond systemic restrictions, the interpersonal aspect also comes into play. Conventional providers note that *"any parent may be*

somewhat apprehensive about disclosing certain alternative treatments if they think the doctor is not going to approve." *"Parents may think that asking about alternative medicine will diminish my opinion of them."* Nevertheless, parents/caregivers experience fewer restrictions in alternative care settings, *"there is more time for appointments,"* and *"more openness on topics of conversation."*

Theme 4 – Time constraints

Time is a significant concern for parents/caregivers. They generally feel that they do not have enough time with conventional providers: *"communication is limited. They focus on their work with my child, but alternative practitioners take the time to answer questions and make suggestions."* Conventional providers also feel that there is not enough time to address all parental concerns during visits. *"I don't have time to do everything during a visit, especially since visits are now shorter; there is not enough time."* *"We used to have more time in the past, but not anymore."* Time is also an issue in alternative care settings, *"my workload is considerable because there are very few speech-language pathologists; we want to spend more time on the intervention, which leaves little time to talk to the parents."*

DISCUSSION

Parents/caregivers communicate with health professionals of both streams. However, there are no formal communication channels between the two streams. Conventional providers and alternative practitioners do not communicate. Where communication does exist, it faces several challenges and barriers (Figure 2).

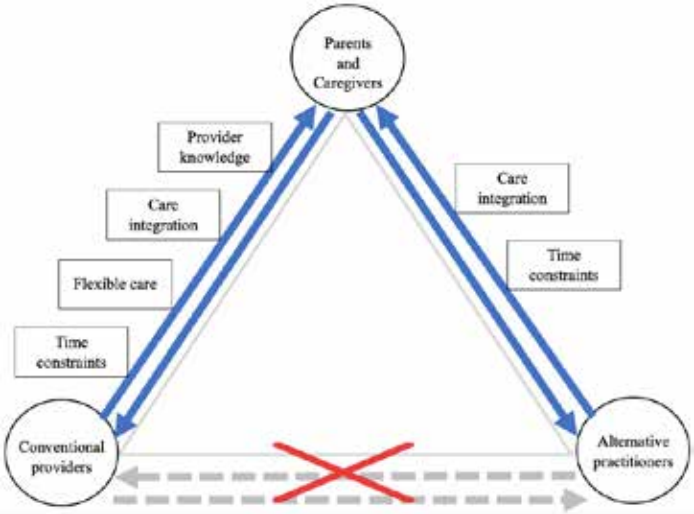

Figure 2. Communication flow between the actors involved in children autism care in Ottawa.

Between parents/caregivers and conventional providers, there is a perceived lack of knowledge of these professionals relating to CAM. There is no continuity of care where CAM is added to supplement care since there is no communication between the professionals of the two streams. There is little flexibility in care. The conventional system offers few openings for alternative medicine use in autism care, making the subject a taboo between most professionals and parents. Finally, time constraints with respect to the length and frequency of visits. Professionals and parents report concerns relating to time. While parents/caregivers perceive that they experience better communication flow with fewer challenges in alternative care settings, care integration and time constraints are an issue. The themes identified closely link to each other, with two themes influenced by two contexts of the ecological model (Figure 3).

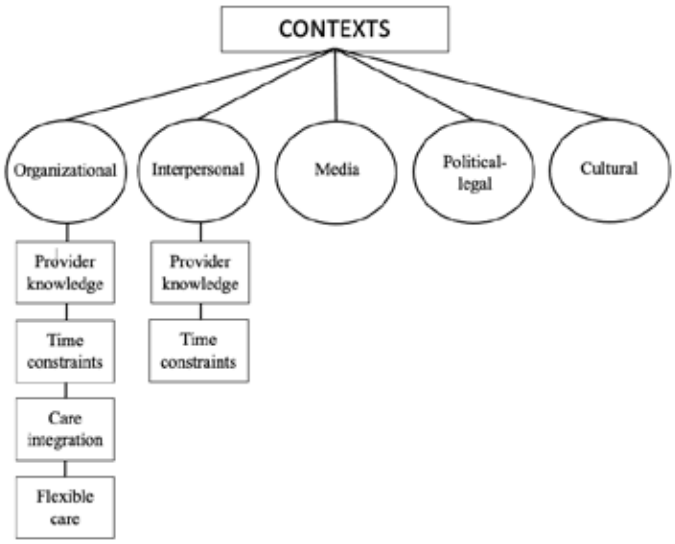

Figure 3. The ecological model and participant identified barriers to communication within the system.

Knowledge links to time and trust. Parents see conventional providers as not particularly knowledgeable regarding alternative medicine, undermining their trust in the provider. In general, autism poses a problem for healthcare professionals who report only moderate levels of autism knowledge.[34,35] Levy et al. indicated that pediatricians and families report knowledge gaps by pediatricians about ASD treatments and community resources and ambiguity regarding the pediatrician's role in ASD care.[9,36] Further, there is little communication between parents and pediatricians about treatment choices. However, a lack of knowledge is not the only reason conventional providers do not discuss alternative medicine. Organizational constraints, financial costs, and a lack of time create barriers to

information-sharing. In general, there is not enough time to discuss everything during a visit.[9,37] The high financial cost of CAM treatments is another concern for providers.[29] They tend to steer away from these costly, unproven treatments.[9]

Knowledge is not a factor in alternative care settings. However, a lack of continuity and time constraints influence communication. Besides the restrictions inherent to the profession, the number of professionals providing alternative treatments is not enough to respond to the increased prevalence of autism cases as reported, making time an issue during visits.

Parents/caregivers experience a lack of flexibility in conventional settings. Many parents report feeling unsupported or uninformed by their general practitioner, specialist or other healthcare professional regarding CAM use with their child.[6] Although perceived as an interpersonal issue, the lack of flexibility on the provider's side stems from organizational constraints, lack of time, and knowledge. While alternative practitioners show more flexibility in terms of time, they are also limited by organizational constraints. These constraints also prevent communication between the two streams. Parents/caregivers are solely responsible for ensuring continuity if they choose to share with the professionals.

From the five contexts examined: organizational, interpersonal, media, political-legal, and cultural, we found that the organizational and interpersonal contexts are the only contexts influencing communication flow within the system. The media, political-legal, and cultural contexts produced no themes in this study. During a parent interview, the media context was briefly reported relating to information searches over the Internet. However, at the time of this study, there were no reported consultations over the internet or email exchanges with care providers or among healthcare professionals. The different sources reported no political-legal issues. Lastly, the cultural context was difficult to assess in the context of this study (limited participants n = 12).

Organizational Context

Barriers such as provider knowledge, care integration, flexibility in care, and time constraints are identified related to this context. The policies and regulations in place for both streams prevent the possibility of communication leading to the perception of a lack of flexibility on providers' parts. Furthermore, parents/caregivers find appointments too short and far apart in conventional care settings. There is not enough time to alleviate their worries. Myers et al. reported parental feelings of not being listened to, including feeling that their concerns were disregarded or doubted.[37] The provider did not take the time to listen to the specific details related to their child. The administration sets the time allotted for each appointment. Parents/caregivers can book a time to discuss specific issues. However, it can take months before they can meet with the provider.

Time constraints also make it difficult for providers to oversee every aspect during appointments. Due to a lack of resources, they must do more in less time. Though generally aware of the existence of alternative medicine and the fact that parents are, in most cases, attracted to its promises, they find it is best not to initiate talks on the matter with the families. The evidence regarding the outcome of such treatments has no scientific basis. Nevertheless, it is reported that parents deplore the fact that there is no real authority on treatments; it would be helpful to know which one to spend all time and money on.[38]

Time is an issue in alternative care settings due to a lack of available service providers. However, parents/caregivers are generally satisfied with the amount of time provided and the timeliness of appointments. Nevertheless, these appointments are paid out-of-pocket. Funding is only allocated through specialized centers for complementary services (e.g., occupational therapy, speech pathology). Because alternative treatments are costly, providers do not initiate talks on the subject to avoid unnecessary expenses for parents/caregivers. They find that directing parents to alternative medicine would imply a rather heavy financial burden when they may not obtain the expected results or even miss out on treatments supported by research.[29,39] However, their silence is perceived as a lack of knowledge of alternative medicine, creating doubts and undermining trust in their relationship with parents/caregivers.

Interpersonal Context

On an interpersonal level, the parents/caregivers' perceived lack of conventional providers' knowledge about alternative medicine makes trust an additional challenge. Trust is the cornerstone of the doctor-patient relationship. It is strongly influenced by what happens during consultations.[26] The *don't ask, don't tell* approach[40] significantly influences communication in conventional settings. Parents/caregivers

perceive the difficulties of finding enough time to discuss and share information with providers in both streams as a lack of flexibility. The professionals on both sides do not communicate with each other either. Providers are open to sharing with alternative medicine practitioners, but there are no provisions for communication between the two streams. Any time spent consulting or preparing files for an alternative practitioner would be unpaid. In general, unless a treatment can show evident benefits, it cannot become part of conventional medical practice and be eligible for financial coverage. For example, exceptions have been made in heart surgery,[41] and some CAM treatments are used in conventional practices.[42] However, with the lack of evidence relating to CAM treatments paired with the heterogeneous nature of ASD, which makes it so that all treatments do not work for all, a potential integration of the two streams is yet to be possible.

While communication is more open in alternative care settings since practitioners are more readily accessible, it also faces barriers. Parents/caregivers may decide to discontinue treatment without communicating their doubt or concern to the practitioner, creating a lack of continuity within the stream.

In sum, looking at our communication flow triangle (Figure 1), a cross-reference of the different themes and the five contexts of the ecological model (Figure 4):

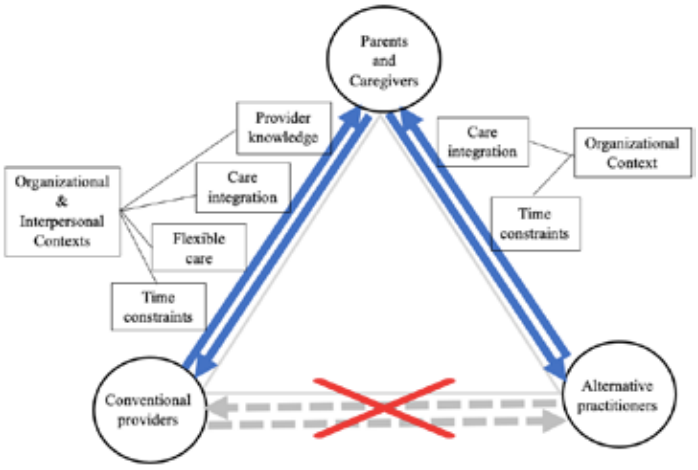

Figure 4. Communication flow and barriers within the system per the contexts of the ecological model.

There is communication between parents/caregivers and conventional providers with influences from the organizational and interpersonal contexts. The identified barriers to communication are lack of knowledge, care integration, flexibility, and time constraints. The organizational context influences communication between parents/caregivers and alternative practitioners, with barriers stemming from a lack of care integration and time constraints. There is no communication between conventional providers and alternative practitioners due to organizational influences. No themes referred to the media, political-legal, and cultural contexts in this study (Figure 3).

Nevertheless, parental beliefs and preferences[43,44] play a significant role in autism care. Despite the lack of evidence relating to CAM usage, many parents use these treatments for their autistic children. Studies focusing on parental decision-making regarding treatment options highlight the parental need for information.[44-46] More opportunities for open communication between all parties involved in the care of autistic children, regardless of CAM status within the system, would be beneficial. These findings align with Wilson et al., who report the necessity of open discussions between parents and providers relating to treatment decisions.[29] In addition, as reported in research over the past decade, more ASD and CAM-related training for healthcare professionals[9,47] would allow better understanding and promote effective parent/caregiver-provider communication.

CONCLUSION

Twelve participants allowed us to describe the communication flow between the parties involved in the care of autistic children in Ottawa, Canada. Despite an underlying resistance to change, the increasing interest in alternative medicine is forcing changes in the healthcare system. Within the themes, the necessity for increased communication between all parties involved in the care of autistic children is evident. These findings contribute to a better understanding of the role of communication in the care management of autism, which has implications for effective autism care. More openings allowing for time to discuss alternative treatments in conventional settings are necessary. CAM-related training for providers would support effective parent/caregiver-provider communication to improve the quality of care for autistic children.

Study Limitations

This study outlines several barriers to communication flow during autism care management in the system in Ottawa. Because this is a perception-based study, participant bias must be considered. Although we were able to have an equal number of participants for each category, the recruitment

difficulties for this study limited our scope of action. Other barriers include a small sample size. The study is specific to Ottawa; it may not be generalizable across the province or other regions in Canada. The parental perceptions are reported from parents/caregivers of young autistic children only; findings may differ with older children.

Implications and Future Directions

Our results provide leads for a better understanding of the role of communication in the care management of autism. Despite several communication barriers, providers increasingly feel the need to communicate with alternative practitioners, if not to work together, to at least gather information about their practices. The lack of evidence of alternative practices remains of great concern, though not diminishing the interest in their use, making communication crucial in this context. Further investigation into ways to promote effective communication may increase care quality for children with autism. Finally, the focus of this research could be replicated in other Canadian cities to establish national results.

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APPENDIX - INTERVIEW GUIDE PER PARTICIPANT CATEGORY

Parent or caregiver of an autistic child using only conventional medicine

1. Your child was diagnosed with autism. How old is he/she?
2. When was the child diagnosed?
3. Have you heard about alternative medicine?
4. What is your definition of alternative medicine?
5. Do you use any alternative methods?
6. What were the doctor's recommendations after the diagnostic?
7. Was a care plan put in place - what does it entail?
8. How often do you have appointments with your child's doctor?
9. What happens during a regular clinical appointment?
10. Can you describe your communication with the doctor?
11. Has alternative medicine been discussed during your appointments?
12. Do you feel comfortable, or would you feel comfortable discussing alternative medicine with your child's doctor?
13. How informed do you feel your child's doctor is about alternative medicine?
14. Do you think integrating conventional and alternative methods would benefit your child's care?
15. What do you feel would be the advantages?
16. What would be the means to allow the integration of conventional and alternative medicine?

Verification questions (If there is no mention during the interview)

- Have you had communications with the care providers in between appointments by phone or e-mail?
- How did you hear about alternative medicine?

Parent or caregiver of an autistic child using only conventional medicine and alternative medicine or alternative medicine only

1. Your child was diagnosed with autism. How old is he/she?
2. When was the child diagnosed?
3. Have you heard about alternative medicine?
4. What is your definition of alternative medicine?
5. Do you use any alternative methods?
6. What were the doctor's recommendations after the diagnostic?
7. Was a care plan put in place - what does it entail?
8. How often do you see your child's doctor and/or alternative practitioner?
9. What happens during a regular appointment with the doctor and/or your child's alternative practitioner?
10. Can you describe your communication with the doctor and/or practitioner?
11. Has alternative medicine been discussed during your appointments with the doctor, and/or has the alternative practitioner asked about the care plan in place for your child during visits?
12. Do you feel comfortable, or would you feel comfortable discussing alternative medicine with your child's doctor?
13. How informed do you feel your child's doctor is about alternative medicine?
14. Do you think integrating conventional and alternative methods would benefit your child's care?
15. What do you feel would be the advantages?
16. What do you think would be the means to allow the integration of conventional and alternative medicine?

Verification questions (If there is no mention during the interview)

- Have you had communications with the care providers in between appointments by phone or e-mail?
- How did you hear about alternative medicine?

Developmental doctor, psychologist, pediatrician, family doctor, who works, or has worked with at least one autistic child

1. What is your area of expertise?
2. Have you had or do you currently have any autistic patients?
3. How often are appointments scheduled with the patients? How long does an average appointment last?
4. After a diagnosis of autism, what does a typical care plan entail?
5. Do you have experience with alternative methods?
6. What is your definition of alternative medicine?
7. Can you describe your communication with the parents?
8. Do you take the initiative to discuss alternative treatments with your patients' parents during regular appointments?
9. Have some parents approached you on the subject of alternative medicine?
10. Do you make prescriptions and/or recommendations about alternative methods?
11. Do you think parents feel comfortable bringing up the subject of alternative medicine during regular appointments?
12. Do you think parents have enough time to discuss the alternative treatment of their child?
13. Would it be advantageous for your patients if their parents discussed the alternative treatments used with you?
14. Would you be ready for a collaboration/exchange with your patients' alternative practitioner?
15. Would the integration of conventional and alternative methods benefit your patients?
16. How would that impact the healthcare system?
17. Do you think the healthcare system has the capacity to support a continuum of integrated care in autism cases?
18. What do you think would be the means to allow the integration of conventional and alternative medicine?

Verification questions (If there is no mention during the interview)

- Have you had communications with the parents in between appointments by phone or e-mail?
- How did you hear about alternative medicine?

Doctor/practitioner using alternative methods, medical and paramedical personnel, who works, or has worked with at least one autistic child

1. What is your area of expertise?
2. Have you had or do you currently have autistic patients?
3. What is your definition of alternative medicine?
4. Why alternative methods for autism care?
5. How often are appointments scheduled with the patients? How long does an average appointment last?
6. Do parents have a choice of alternative treatment, or are there typical methods used in autism cases?
7. Can you describe your communication with the parents?
8. Do you keep informed about new alternative methods and discuss them with your patients' parents?
9. Do you feel that parents are comfortable questioning the alternative methods prescribed during appointments?
10. Are you knowledgeable about the conventional medical care plan process?
11. Do you make any prescriptions and/or recommendations about conventional medicine?
12. Do you allow time during appointments for the parents to discuss the medication prescribed by your patients' doctors?
13. Would it be advantageous for the children if their parents discussed the alternative treatments used with the doctor during appointments?
14. Would you be ready to collaborate/exchange with your patients' doctors?
15. Do you think integrating conventional and alternative methods would benefit autistic children?
16. How would that impact the healthcare system?
17. Do you think the healthcare system has the capacity to support a continuum of integrated care in autism cases?
18. What do you think would be the means to allow the integration of conventional and alternative medicine?

Verification questions (If there is no mention during the interview)

- Have you had communications with the parents in between appointments by phone or e-mail?
- How did you hear about alternative medicine?

Isopropyl Alcohol as Anti-Emetic Therapy in the Emergency Department: Study Protocol for a Multi-Center Randomized Controlled Trial

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Date Submitted: November 10, 2021
Date Accepted: March 29, 2022
Date Published: July 19, 2024

DOI: https://doi.org//10.18192/uojm.v13i1.6100

Keywords: *emergency department, isopropyl alcohol, inhalation, nausea, vomiting*

ABSTRACT

Background: Nausea and vomiting are common and distressing presenting complaint in Emergency Departments (EDs). There is no definite evidence to support the superiority of any anti-emetic therapy over another or over placebo. Identification of an effective anti-emetic therapy in the ED setting with minimal side effects would be of great benefit. Isopropyl alcohol inhalation has been reported to be an effective treatment for post-operative nausea and vomiting, with no reported adverse events. This manuscript presents the protocol for a study aiming to determine if nasally inhaled isopropyl alcohol swabs are effective in alleviating nausea and/or vomiting in patients presenting to the ED with a chief complaint of nausea and/or vomiting.

Methods: We will conduct a randomized, controlled, multicenter trial with three subject arms: 1) nasally inhaled isopropyl alcohol swabs every 10 minutes for a total of one hour, 2) nasally inhaled isopropyl alcohol swabs every 20 minutes for a total of one hour, or 3) no intervention. 135 participants ≥18 years old and presenting to the ED with a chief complaint of nausea and/or vomiting with a level of 3 or greater on a verbal numeric rating scale (NRS) will be recruited for a duration of two hours. The primary outcome measure is the mean reduction in nausea scores, comparing the pre-intervention score to the lowest post-intervention nausea score. The secondary outcome measures will be participant satisfaction scores using a verbal NRS, receipt of any rescue anti-emetic medications, a number of vomiting episodes during ED stay, ED length of stay, and participant disposition (admission or discharge home).

Conclusion: This study will determine the efficacy of inhaled isopropyl alcohol swabs in treating patients with nausea and vomiting in the emergency department. By determining the optimal dosing frequency, this has the potential to guide future triage protocols incorporating this therapy to provide earlier symptomatic relief to patients while improving patient satisfaction and efficiently using in-patient resources.

RÉSUMÉ

Contexte: Les nausées et les vomissements sont des symptômes fréquents et pénibles dans les services d'urgence. Il n'existe pas de preuves formelles de la supériorité d'un traitement antiémétique par rapport à un autre ou par rapport à un placebo. L'identification d'une thérapie antiémétique efficace dans le contexte des urgences, avec des effets secondaires minimes, serait d'une grande utilité. L'inhalation d'alcool isopropylique s'est révélée être un traitement efficace contre les nausées et vomissements postopératoires, sans effets indésirables signalés. Ce manuscrit présente le protocole d'une étude visant à déterminer si les tampons d'alcool isopropylique inhalés par voie nasale sont efficaces pour soulager les nausées et/ou les vomissements chez les patients se présentant aux urgences avec une plainte principale de nausées et/ou de vomissements.

Méthodes: Nous mènerons un essai randomisé, contrôlé, multicentrique avec trois groupes de sujets: 1) inhalation nasale de tampons d'alcool isopropylique toutes les 10 minutes pendant une heure au total, 2) inhalation nasale de tampons d'alcool isopropylique toutes les 20 minutes pendant une heure au total, ou 3) pas d'intervention. 135 participants âgés de ≥18 ans et se présentant aux urgences avec une plainte principale de nausées et/ou de vomissements avec un niveau de 3 ou plus sur une échelle d'évaluation numérique verbale (ÉÉN) seront recrutés pour une durée de deux heures. Le principal critère de jugement est la réduction moyenne des scores de nausées, en comparant le score avant l'intervention au score le plus bas après l'intervention. Les résultats secondaires seront les scores de satisfaction des participants à l'aide d'une échelle verbale ÉÉN, la réception de médicaments antiémétiques de secours, le nombre d'épisodes de vomissements pendant le séjour aux urgences, la durée du séjour aux urgences et la disposition des participants (admission ou sortie à domicile).

Conclusion: Cette étude déterminera l'efficacité des tampons d'alcool isopropylique inhalés dans le traitement des patients souffrant de nausées et de vomissements au service des urgences. En déterminant la fréquence de dosage optimale, elle pourrait guider les futurs protocoles de triage intégrant cette thérapie afin de soulager plus rapidement les symptômes des patients tout en améliorant leur satisfaction et en utilisant efficacement les ressources hospitalières.

INTRODUCTION

Nausea and vomiting are common and distressing presenting complaints in Canadian Emergency Departments (EDs). The frequently used anti-emetic medications used to treat nausea and vomiting in the ED, including ondansetron, metoclopramide and dimenhydrinate, have proven efficacious in the treatment of specific patient populations (i.e. chemotherapy patients and post-operative nausea and vomiting).[1,2] However, in the ED setting, there is no definite evidence to support the superiority of any one medication over another or the superiority of any medication over a placebo.[3] Furthermore, these medications have been associated with adverse effects, including a feeling of internal restlessness, sedation, and life-threatening heart rhythm abnormalities.[3,4] These medications also have the potential to interact with a patient's own medications, limiting their use before the patient is assessed by the treating physician.

Emerging evidence exists supporting the use of nasally inhaled isopropyl alcohol swabs as anti-emetic therapy. While the mechanism of action of isopropyl alcohol's anti-emetic effect remains unclear, theories exist that this effect may be related to olfactory distraction. Multiple studies report isopropyl alcohol inhalation as an effective treatment for post-operative nausea and vomiting when compared to placebo, with no reported adverse events.[5] This relatively inexpensive substance is widely available in most health care settings in the form of swabs used in the routine course of delivering care as an antiseptic skin cleanser. Two previous studies in the United States have evaluated the use of inhaled isopropyl alcohol swabs in alleviating nausea and vomiting in the ED setting.[6,7] A 2016 study by Beadle et al. demonstrated superior nausea relief using inhaled isopropyl alcohol swabs compared to an inhaled placebo. Moreover, a 2018 study by April et al. demonstrated that isopropyl alcohol swabs, with or without oral ondansetron, provided greater nausea relief than oral ondansetron alone.[6,7] These two studies in the ED setting also did not report any adverse events.[6,7]

The 2016 study by Beadle et al. has several important limitations. This was a single-center military hospital study, which only measured nausea scores 10 minutes after isopropyl alcohol swab inhalation and lacked other important outcomes, such as the number of vomiting episodes, use of rescue anti-emetics, ED length of stay and admission rates. The 2018 study by April et. al. also has limitations. Mainly, alcohol swabs were used as often as required by participants, and the dosing frequency of inhalations was not measured. They also excluded patients who had a peripheral IV catheter inserted on arrival, which may suggest that patients with more severe symptoms of nausea and vomiting requiring IV anti-emetics were excluded.

Identification of effective anti-emetic therapy in the ED setting with minimal side effects would be of great benefit to the ED provider. Our goal is to add to the current body of evidence on the use of isopropyl alcohol in alleviating nausea and vomiting in the ED setting, particularly by determining which dosing frequency of isopropyl alcohol inhalation yields the most effective nausea relief by randomizing patients to different inhalation frequencies. This may help to guide future triage protocols enabling isopropyl alcohol inhalation before provider evaluation to improve treatment of nausea and patient satisfaction. In the current state of ED crowding, the ability to adequately control a patient's symptoms at triage may help decrease a patient's length of stay as well as the number of patients requiring beds. In addition, from a cost-savings perspective, alcohol swabs are a relatively inexpensive therapy as compared to many commonly administered anti-emetics.

Given that there is no universally accepted standard of care in treating nausea and vomiting in the emergency department setting, there will be no treatment group for comparison.

The primary objective of this study is to determine if nasally inhaled isopropyl alcohol swabs are effective in alleviating nausea and/or vomiting in patients presenting to the ED with a chief complaint of nausea and/or vomiting. The secondary objectives are to determine the optimal dosing frequency of nasally inhaled isopropyl alcohol swabs as either every 10 minutes or every 20 minutes in patients presenting to the ED with a chief complaint of nausea and/or vomiting. Other secondary objectives are to determine the effect of nasally inhaled isopropyl alcohol swabs on:

- Patient satisfaction
- Use of rescue anti-emetics
- Number of vomiting episodes during ED stay
- Patient's ED length of stay
- Patient's disposition either discharged from or admitted to hospital

METHODS

Study Design and Population

This study is designed as a randomized, controlled, multicenter trial. Subjects will be recruited in two urban, tertiary EDs in [blinded]. In each center, there are approximately 2000 patients presenting to the emergency department with a chief complaint of nausea and/or vomiting per year.

The inclusion criteria will be subjects who are over 18 years old and present to the ED with a chief complaint of nausea and/or vomiting with a level of 3 or greater on a verbal numeric rating scale ranging from 1-to-10. The exclusion criteria will be: subjects unable to breathe through their nares (i.e. rhinitis), pregnant, already received an anti-emetic within the past 24 hours (including while in ED triage), have chronic nausea (> 1 month), have a known allergy to isopropyl alcohol, who are nasally sensitive to inhaled chemical products or have an altered mental status or underlying cognitive impairment.

Patients who meet all inclusion criteria and none of the exclusion criteria will be offered the opportunity to participate in the study and provided with all the relevant information verbally and in writing. A convenience sample of potential study subjects will be identified by the research team during periods when available to enroll subjects. Participants will be recruited in the ED by the research team while in the waiting room or shortly after arrival to their assigned ED room, before the arrival of their treating physician and before any treatment is provided. The research team will speak with the emergency care team (i.e. nurses or physicians), who will obtain permission from the patient for the research team to approach the patient regarding the study before any anti-emetics are administered to the patient. There will be no financial compensation for patient participation in the trial.

All patients who give consent for participation and who fulfil the inclusion criteria will be randomized. The details regarding participant consent forms are outlined in Appendix 1. The research team will be responsible for obtaining written consent, enrolling patients and generating the allocation sequence.

The Ottawa Health Science Network Research Ethics Board (OHSN-REB) approved the protocol. A Natural Health Product Clinical Trial Application will be required by Health Canada prior to initiation of the study.

Trial Registration

ClinicalTrials.gov: NCT04464915

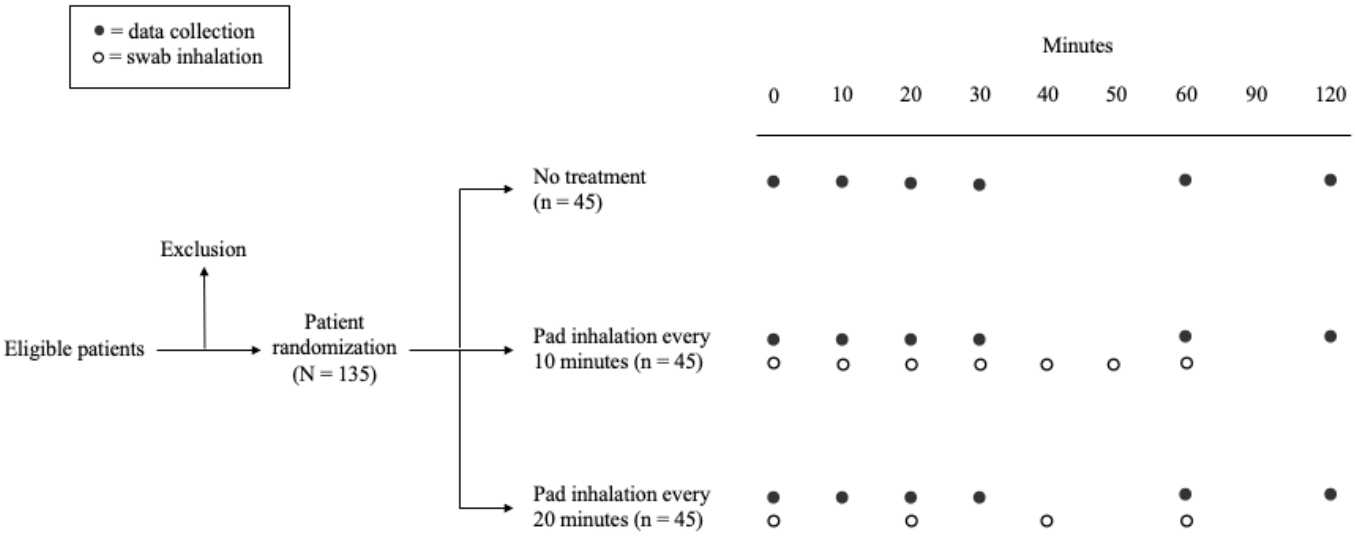

Figure 1. Flow diagram of study with identification of eligible patients and randomization to treatment arms, with timeline demonstrating data collection and swab inhalation time points.

Randomization

Participants will be randomly assigned to one of three treatment arms with a 1:1:1 allocation as per a computer-generated randomization schedule using permuted blocks of 6: 1) nasally inhaled isopropyl alcohol swabs every 10 minutes for a total of one hour; 2) nasally inhaled isopropyl alcohol swabs every 20 minutes for a total of one hour and 3) no intervention (Figure 1).

Allocation concealment will be ensured, as the service will not release the randomization code until the patient has been recruited into the trial. The research team will be responsible for generating the allocation sequence. Due to the nature of the intervention, neither participants nor research staff can be blinded to allocation. Given that blinding the scent of isopropyl alcohol would be challenging, there will be a no-treatment arm rather than a placebo group. Data analysts will, however, be blinded.

Retention

Given this relatively short study duration of two hours with frequent follow-up from the research team to obtain nausea scores, it is anticipated that this study will have a high level of participant retention which will the maximize completeness of data collection. Participants who voluntarily withdraw early from the study will be asked for permission to use their data. The participant will be asked if they wish to withdraw from the study intervention, however, permit data obtained to date to be included in the analysis, or withdraw from study the intervention and indicate that the data collected to date cannot be used in the final analysis.

Interventions

The intervention is Isopropyl alcohol swabs. Swabs will be administered by instructing patients to take one deep inhalation of a swab held 1-2cm below the nares. Intervals of administration will be either every 10 minutes or every 20 minutes for a total of one hour depending on the randomization arm. New swabs will be provided in a manufactured, sealed pouch as distributed by the manufacturer to the patient for each inhalation.

The active study duration will be two hours for each patient while in the ED from the time of randomization until the collection of nausea scores are completed after a total of two hours. There will be no further follow-up. The assigned study intervention may need to be discontinued by trial investigators if there are any adverse events, such as allergic reactions.

Patient compliance will be monitored by the research team administering the isopropyl alcohol swabs. The research team will hand one packaged swab at a time to the subject and observe for one full, adequate inhalation at the designated interval of every 10 minutes or every 20 minutes to ensure adequate compliance.

Patients who have used an anti-emetic in the past 24 hours will be excluded from the study. However, there will be no restrictions on the use of concomitant medications during the trial. Participants should continue to take medications for other conditions as normal. Any additional medications or treatments will be permitted by the treating physician during the trial, including any rescue anti-emetics.

Outcome Measures

The primary outcome reflecting the efficacy of the study intervention is the mean reduction in nausea scores comparing pre-intervention scores to the lowest post-intervention scores measured throughout the two hours of intervention, or the last nausea score before a rescue anti-emetic is administered by the treating physician.

The intervention will be determined to be effective if there is a reduction by 3 or more points on a self-reported 10-point verbal numeric scale ranging from 1-10, labelled "no nausea" at the left end (1) and "worst nausea imaginable" at the right end (10). This value was chosen based on values from previous studies using similar nausea scores.[6,7]

The verbal numeric rating scale is highly reliable among adult patients in the ED with nausea and/or vomiting and correlates highly with the visual analogue scale.[8] It has been shown to reliably differentiate between initial severity categories, change in severity, and patient satisfaction categories.[8] The numeric rating scale was chosen because of its practical use in the ED.

The secondary outcomes reflecting the efficacy of the study intervention are participant satisfaction scores, the receipt of any rescue anti-emetic medications, a number of vomiting episodes during ED stay (as defined by forceful expulsion of gastric content excluding non-productive retching or drooling), ED length of stay, and patient disposition (discharge from or admission to hospital). Satisfaction scores will be measured using a self-reported 5-point verbal numeric scale ranging from 1-5, labeled "very unsatisfied" at the left end (1) and "very satisfied" at the right end (5).

Sample Size

The goal is to estimate the efficacy of nasally inhaled isopropyl alcohol in alleviating nausea and/or vomiting in study subjects by measuring the reduction in patient-reported nausea scores by comparing pre-intervention scores to the lowest post-intervention scores. The minimally clinically significant difference is assumed to be 3 points on a self-reported 10-point verbal numeric scale ranging from 1-to 10. For $\alpha=0.025$ and $\beta=0.80$ using a t-test and a standard deviation of 3 points, the sample size required is 45 per participant's arm (135 participants total).

Data Collection

Primary outcome: Nausea scores will be measured at baseline before the intervention, 10 minutes after initiating the intervention, 20 minutes after initiating the intervention, 30 minutes after initiating the intervention, and then every 30 minutes for a total of two hours throughout the subject's ED visit.

Secondary Outcomes: Subject satisfaction scores will be measured either after two hours or when the final nausea score is obtained before a rescue anti-emetic is administered by the treating physician.

The receipt of any additional anti-emetic therapy will be documented, including medication, dosing and frequency. The number of vomiting episodes since the preceding data collection period will be documented. The participant's ED length of stay in minutes will be documented. The participant's disposition from the ED will be documented, as either discharged home or admitted to the hospital.

Exploratory Outcomes: The study will collect demographic information from the patient, including age, sex, tobacco use, alcohol use, illicit drug use, and medical comorbidities. Other relevant clinical information will be obtained, including duration of nausea and/or vomiting, presence of any additional symptoms, investigations and/or interventions completed by the ED physician, and final diagnosis at the time of ED disposition.

Statistical Analysis

The primary outcome, i.e., the mean reduction in nausea scores, will be analyzed using repeated measures linear regression analysis. The study arm, time and study arm by

time will be included as fixed covariates, and the correlation in repeated measures on the same subject over time will be modeled using a suitable covariance structure. Least square mean differences, together with 95% Confidence Intervals, will be used to express the treatment effect, comparing each of the intervention arms to the control arm. The statistical significance of each pairwise comparison will be judged at the 2.5% level to maintain the overall level at 5%. A similar approach will be used for ED lengths of stay (with transformation to improve normality if necessary). The number of vomiting episodes and receipt of antiemetic drugs will be analyzed using Poisson or logistic regression as appropriate. Participant baseline characteristics will be summarized with descriptive statistics with 95% confidence intervals.

All analyses will be with the intention to treat, considering all patients as randomized regardless of whether they received the randomized treatment. Dropouts (essentially, participants who withdraw consent for continued follow-up) will be included in the analysis by modern imputation methods for missing data. After the imputations are completed, all of the data (complete and imputed) will be combined, and the analysis performed.

CONCLUSION

Nausea and vomiting are common and distressing complaints in patients presenting to Canadian emergency departments. Identification of effective anti-emetic therapy in the ED setting with minimal side effects would be of great benefit to the ED provider. The use of inhaled isopropyl alcohol swabs has been proven to be efficacious in post-operative nausea and vomiting, and two recent ED studies have shown promising results in treating nausea and vomiting, with no reported adverse effects. This study will determine the efficacy of inhaled isopropyl alcohol swabs by determining the optimal dosing frequency that achieves adequate anti-emetic action, potentially guiding future triage protocols to incorporate this therapy. We strongly suspect that once this study is performed, it will be useful for ED physicians in treating nausea and vomiting in the ED.

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APPENDIX 1 - INFORMED CONSENT MATERIALS

Main Informed Consent Form for Participation in a Research Study

Study Title: Isopropyl Alcohol Inhalation as Anti-Emetic Therapy in the Emergency Department

OHSN-REB Number: [Blinded]

Study Doctor: [Blinded]

Introduction
You are being invited to participate in a clinical trial/study (a type of study that involves research). You are invited to participate in this trial/study because you presented to the emergency department with nausea and/or vomiting. This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Please take your time in making your decision. You may find it helpful to discuss it with your friends and family.

Taking part in this study is voluntary. You have the option to not participate at all or you may choose to leave the study at any time. Whatever you choose, it will not affect the usual medical care that you receive outside the study.

Is there a conflict of interest?
There are no conflicts of interest to declare related to this study.

What is the background information for this study?
Nausea and vomiting is a common presenting complaint in Canadian emergency departments. Nausea medications are commonly used to help relieve these symptoms, however not one has been proven to be more effective than the other, and many are associated with side effects. Inhalation of alcohol swabs has been shown to be an effective therapy in relieving nausea and vomiting after surgery. This relatively inexpensive substance is widely available with no known side effects, which would be of great benefit in the emergency department in treating nausea.

Why is this study being done?
The purpose of this study is to determine if alcohol swabs are effective in relieving nausea and/or vomiting in patients the emergency department. The purpose of this study is to find out whether it is better to be treated with alcohol swab inhalation, or better to receive no additional treatment. To do this, some of the participants in this study will receive inhaled alcohol swabs, and some will receive no treatment.

What other choices are there?
You do not have to take part in this study in order to receive treatment or care. While there is no universally agreed upon standard care for the treatment of nausea/vomiting, other options may include nausea medications such as Gravol.

How many people will take part in this study?
It is anticipated that about 135 people will take part in this study, from research sites located at [blinded].

This study should take 3 months to complete and the results should be known in about 6 months.

Assignment to a Group
If you decide to participate then you will be “randomized” into one of the groups described below. Randomization means that you are put into a group by chance (like flipping a coin). There is no way to predict which group you will be assigned to. You will have a one in three chance of being placed in any group. Neither you or the research team can choose what group you will be in.

What is the study intervention?
Group 1 (Experimental Intervention):
If you are randomized to this group, you will be instructed to hold an alcohol swab 1-2cm from your nose and take one deep inhalation every 10 minutes for a total of one hour. We will record your nausea severity on a scale of 1 to 10 every 10 minutes for 30 minutes, and then every 30 minutes for a total of two hours.
Group 2 (Experimental Intervention):
If you are randomized to this group, you will be instructed to hold an alcohol swab 1-2cm from your nose and take one deep inhalation every 20 minutes for a total of one hour. We will record your nausea severity on a scale of 1 to 10 every 10 minutes for 30 minutes, and then every 30 minutes for a total of two hours.
Group 3 (Non-Experimental):
If you are randomized to this group, you will receive no intervention. We will record your nausea severity on a scale of 1 to 10 every 10 minutes for 30 minutes, and then every 30 minutes for a total of two hours.

What else do I need to know about the study intervention?
If you decide to take part in this study, your treating doctor can still decide to provide you with usual treatment, including nausea medications. If your treating doctor does decide to provide you with nausea medications, the study team will stop administering any study intervention and use your nausea scores up until the medication is given.

How long will participants be in the study?
The study intervention will last for about 1 hour. Your nausea score will be collected for a total of 2 hours.

Can participants choose to leave the study?
You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the research team.

You may withdraw your permission to use information that was collected about you for this study at any time by letting the research team know. However, this would also mean that you withdraw from the study.

Can participation in this study end early?
Study participants may be withdrawn from the study at the discretion of the research team due to a safety concern or if judged to be non-compliant with the trial procedures.

What are the risks or harms of participating in this study?
While there have been no previous studies showing side effects from inhalation of alcohol swabs, there may be side effects that are not expected, such as irritation to the nose and allergic reactions. You should discuss these with the research team. The research team will watch you closely to see if you have side effects.

What are the benefits of participating in this study?
If you agree to take part in this study, the experimental intervention may or may not be of direct benefit to you in providing relief from nausea and/or vomiting. We hope the information learned from this study will help other people with nausea and vomiting in the future.

How will participant information be kept confidential?
If you decide to participate in this study, the research team will only collect the information they need for this study.

Records identifying you at this center will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) medical records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

- [blinded]Research Ethics Board who oversees the ethical conduct of this study.
- [blinded] to oversee the conduct of research at this location

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Your name, address, email, or other information that may directly identify you will not be used. The records received by these organizations may contain your participant code, age, and sex/gender.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be analyzed and will be published/presented to the scientific community at meetings and in journals. Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

A copy of the consent form that you sign to enter the study may be included in your health record/hospital chart.

Will family doctors/health care providers know who is participating in this study?
Your family doctor/health care provider will not be informed by the study team that you are taking part in the study. You can choose to let your family doctor/health care provider know, if you like.

Will information about this study be available online?
A description of this clinical trial/study will be available on https://clinicaltrials.gov. This website will not include information that can identify you. You can search this website at any time. This research study can be found on the above listed website by using the clinical trial registration number NCT04464915.

What is the cost to participants?
Participation in this study will not involve any additional costs to you or your private health care insurance.

Are study participants paid to be in this study?
You will not be paid for taking part in this study.

What are the rights of participants in a research study?
You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please contact the research team.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form you do not give up any of your legal rights against the research team nor does this form relieve the study team of their legal and professional responsibilities. You will be given a copy of this signed and dated consent form prior to participating in this study.

What if researchers discover something about a research participant?
If any new clinically important information about your health is obtained as a result of your participation in this study, you will be given the opportunity to decide whether you wish to be made aware of that information.

Whom do participants contact for questions?
If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to your study doctor, or the doctor who oversees the study at this institution. That person is:

Dr. [blinded]
Principal Investigator Name Telephone

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. Please contact The[blinded] Research Ethics Board, Chairperson at 613-798-5555 extension 16719.

Study Title: Isopropyl Alcohol Inhalation as Anti-Emetic Therapy in the Emergency Department

Signatures

- All my questions have been answered,
- I understand the information within this informed consent form,
- I allow access to medical records and transfer of specimens and related personal health information as explained in this consent form,
- I do not give up any of my legal rights by signing this consent form,
- I agree, or agree to allow the person I am responsible for, to take part in this study.

Signature of Participant	Printed Name	Date
Signature of Person Conducting the Consent Discussion	Printed Name and Role	Date

Study Title: Isopropyl Alcohol Inhalation as Anti-Emetic Therapy in the Emergency Department

Participant Assistance

Complete the following declaration only if the participant is <u>unable to read</u>:

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to the participant, and any questions have been answered.

Signature of Impartial Witness	Printed Name	Date

Relationship to Participant

Complete the following declaration only if the participant has <u>limited proficiency in the language in which the consent form is written and interpretation was provided</u> as follows:

☐ The person signing below acted as an interpreter, and attests that this study as set out in the consent form is accurately sight translated and/or interpreted, and that interpretation was provided on questions, responses and in additional discussion arising from this process.

Signature of Interpreter	Printed Name	Date

Quality Improvement Opportunities for Post-Discharge Urine Culture Follow-Up in a Tertiary Care Emergency Department: A Pilot Study

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Date Submitted: September 28, 2022
Date Accepted: May 19, 2023
Date Published: July 19, 2024

DOI: https://doi.org//10.18192/uojm.v14i1.6502

Keywords: *quality improvement, quality assurance, urine culture, emergency department*

ABSTRACT

Objectives: The development and evaluation of institutional quality assurance processes are important to address the follow up of abnormal test results ordered in the emergency department (ED). We conducted a health records review at an academic tertiary care ED to understand the process and times taken to follow up post-discharge urine culture results transferred to physicians for review.

Methods: All patients (age ≥18 years) who were seen and discharged between July 1, 2020 and June 30, 2021 and had a urine culture flagged for review were eligible for inclusion. We randomly selected 100 patients, abstracted follow-up times, and reported descriptive statistics.

Results: Sixty-five patients were initially identified as requiring further follow-up for their culture results. Nearly 80% of these patients required new, additional, or revised antimicrobial therapy. Overall, the mean time from ED discharge to follow-up completion was 3.4 days (SD 2.1 days). The longest contributor was the time for transfer of results from nurses to physicians for review at 1.4 days (SD 1.2 days).

Conclusions: We demonstrated considerable delay in the follow-up of urine culture results requiring physician review. Future work should address opportunities for reducing times to follow-up, including semi-automation of benign culture results and capture of key patient demographic information in the electronic medical record.

RÉSUMÉ

Objectifs
Le développement et l'évaluation des processus institutionnels d'assurance qualité sont importants pour assurer le suivi des résultats d'examens anormaux demandés dans les services d'urgences hospitaliers. Nous avons procédé à une analyse des dossiers médicaux dans un service d'urgence universitaire de soins tertiaires afin de comprendre le processus et les délais de suivi des résultats de culture d'urine, transmis aux médecins pour revue, après la sortie de l'hôpital.

Méthodes
Tous les patients (âge ≥18 ans) qui ont été vus et sortis entre le 1er juillet 2020 et le 30 juin 2021 et qui avaient une culture d'urine signalée pour revue étaient éligibles pour inclusion. Nous avons sélectionné au hasard 100 patients, résumé les temps de suivi et rapporté les statistiques descriptives.

Résultats
Soixante-cinq patients ont été initialement identifiés comme nécessitant un suivi supplémentaire pour leurs résultats de culture. Près de 80 % de ces patients ont eu besoin d'un nouveau traitement antimicrobien, d'un traitement supplémentaire ou d'une révision du traitement antimicrobien. Dans l'ensemble, le délai moyen entre la sortie des services d'urgences et la fin du suivi était de 3,4 jours (écart-type : 2,1 jours). Le plus long délai identifié a été celui du transfert des résultats des infirmières aux médecins pour examen, soit 1,4 jour (écart-type : 1,2 jour).

Conclusions
Nous avons mis en évidence un retard considérable dans le suivi des résultats des cultures d'urine nécessitant un examen par un médecin. Les travaux futurs devraient porter sur les possibilités de réduire les délais de suivi, y compris la semi-automatisation des résultats de cultures bénignes et la saisie des informations démographiques clés du patient dans le dossier médical électronique.

INTRODUCTION

Urinary tract infections are common with patients that are frequently being seen and treated in the emergency department (ED).[1] As part of the ED work-up, urine cultures are often ordered, with results pending at the time of discharge. The follow-up of culture results, including review and communication to patients and/or their primary care providers, is important to 1) ensure patients receive appropriate antimicrobial therapy and 2) meet regulatory responsibilities relating to the management of tests.[2]

Institutions have developed quality assurance (QA) processes to ensure that clinically significant test results are conveyed to patients or their primary care providers and to implement required treatment changes. Our local QA process for test follow-up relies on physicians and nurses using a two-step process. Imaging, laboratory, and microbiological results that are received after patient disposition are reviewed by a QA nurse who forwards any results requiring physician action to a physician assigned to the Clinical Decision Unit (CDU) for an eight-hour shift. The CDU physician balances the follow-up of test results with taking calls from outside hospitals and assisting with resuscitations or procedural sedation. Similarly, the QA nurse balances QA tasks by providing back-up nursing support throughout the department.

A recent systematic review examined QA processes and found that dedicated staff increased the likelihood of successful test follow-up.[3] However, the use of personnel can be costly with equivocal outcomes.[4,5] For example, one study highlighted the use of a pharmacist-led program, but the time to follow-up clinically significant culture results nearly doubled following the introduction of the intervention.[5] To set the stage for future quality improvement work, we performed a health records review to 1) calculate the times taken for key steps in the post-discharge follow-up process for review of positive urine cultures ordered in the ED and 2) describe the characteristics of culture results that required follow-up. We hypothesized that the time from identification and transfer of results to physician action would be the longest stage in the follow-up process and aimed to identify associations between patient or culture result characteristics and this stage.

METHODS

Study Design and Setting

We conducted a health records review of patients presenting to one of the campuses of an academic tertiary care ED with approximately 80,000 patient visits annually. This study received local research ethics board approval (20210645-01H).

Urine Culture Ordering and Follow-up Processes

ED attending or resident physicians order urine cultures in the electronic medical record (Epic). At the study site, a pathway for urine culture exists for patients who are positive for leukocytes or nitrates on point-of-care or microscopy testing. However, these guidelines are not commonly followed, and urine cultures are ordered based on clinical context. Once final culture results (microbiological growth and sensitivities) have been reported, the QA nurse receives notifications of results in a specific message basket within Epic for all tests with results reported after patient disposition. These notifications are received on a rolling basis. The QA nurse opens the patient chart, reviews the specific encounter, culture result, and discharge disposition, and determines if an antibiotic was prescribed at discharge. If a physician action is indicated (e.g., a new order for antibiotic treatment is indicated), the QA nurse then sends an Epic message to the QA physician on duty for that day. Otherwise, the nurse performs a follow-up and closes the file.

If the patient is on an antibiotic for which the microbe is sensitive, the QA physician notifies the nurse in Epic that no further action is required. If a change in treatment is required or the patient requires follow-up, the QA physician similarly notifies the nurse in Epic. If an action is required, the QA nurse contacts the patient first to notify them of the abnormal result and the treatment plan. If a new prescription is required, the nurse faxes it to the pharmacy provided by the patient or advises the patient to pick it up from the ED. Finally, the QA nurse documents the date and time the follow-up was completed.

Participants

All patients aged 18 and above who were seen and discharged between July 1, 2020, and June 30, 2021, and found to have a positive urine culture flagged for the QA physician for review after their discharge were eligible for inclusion. Patients were excluded if they left without being seen or against medical advice.

Data Collection

We generated a list of patients (n=243) in Epic at the study site who met inclusion and exclusion criteria. The report also included data on the dates and times of the sequential steps in the QA follow-up process and the number and types of organisms identified in the urine culture. As this study was exploratory in nature, no sample size calculation was performed. One hundred patient charts were selected using a computer-based random number generator, and additional data were abstracted using a structured data collection form. Appendix 1 outlines all data that was collected for the project.

Data Analysis

We calculated times for various steps in the process. We then explored whether the time from the transfer of the result (to the physician) to physician action ("time to action") was associated with the patient [sex; place of residence (home or facility); Canadian Triage Acuity Score – (CTAS), presence of an antibiotic allergy, renal function (creatinine), or corrected QT (QTc) interval], or microbiological factors (number of organisms grown, number of sensitive antibiotics) factors using Pearson Correlation Coefficient, t-test or Analysis of Variance (ANOVA), as appropriate. All statistical analyses were completed in SAS 9.4.6 All analyses were completed with a significance level of 0.05 unless otherwise stated.

RESULTS

Characteristics of patients requiring follow-up

Of the 100 patients with positive urine culture [mean age 66.4 years (SD 24.6 years), 59% female (95% CI 49.2-68.1%)] were included in the study, 65 patients (mean age 71.0 years, SD 21.5) required further follow-up. CTAS scores were 2 in 26.2% (95% CI 17.0-38.0%; n=17), 3 for 67.7% (95% CI 55.6-77.8%; n=44), and 4 for 6.1% (95% CI 2.4-14.8%; n=4). No patients were triaged as CTAS 1 or 5. 84.6% (95% CI 74.0-91.4%; n=55) of cultures requiring follow-up grew a single organism. The most common bacteria grown was *Escherichia coli*.

Process times and outcomes

The QA process for urine culture follow-up is illustrated in Figure 1. The mean time from ED discharge to urine culture results appearing in Epic was 1.3 days (SD 1.5 days). The mean time from culture results appearing in Epic to transfer for physician review was 1.4 days (SD 1.2 days). The mean time for the physician to provide further follow-up instructions after receiving nursing notification was 2.6 hours (SD 6.6 hours). This time was not significantly

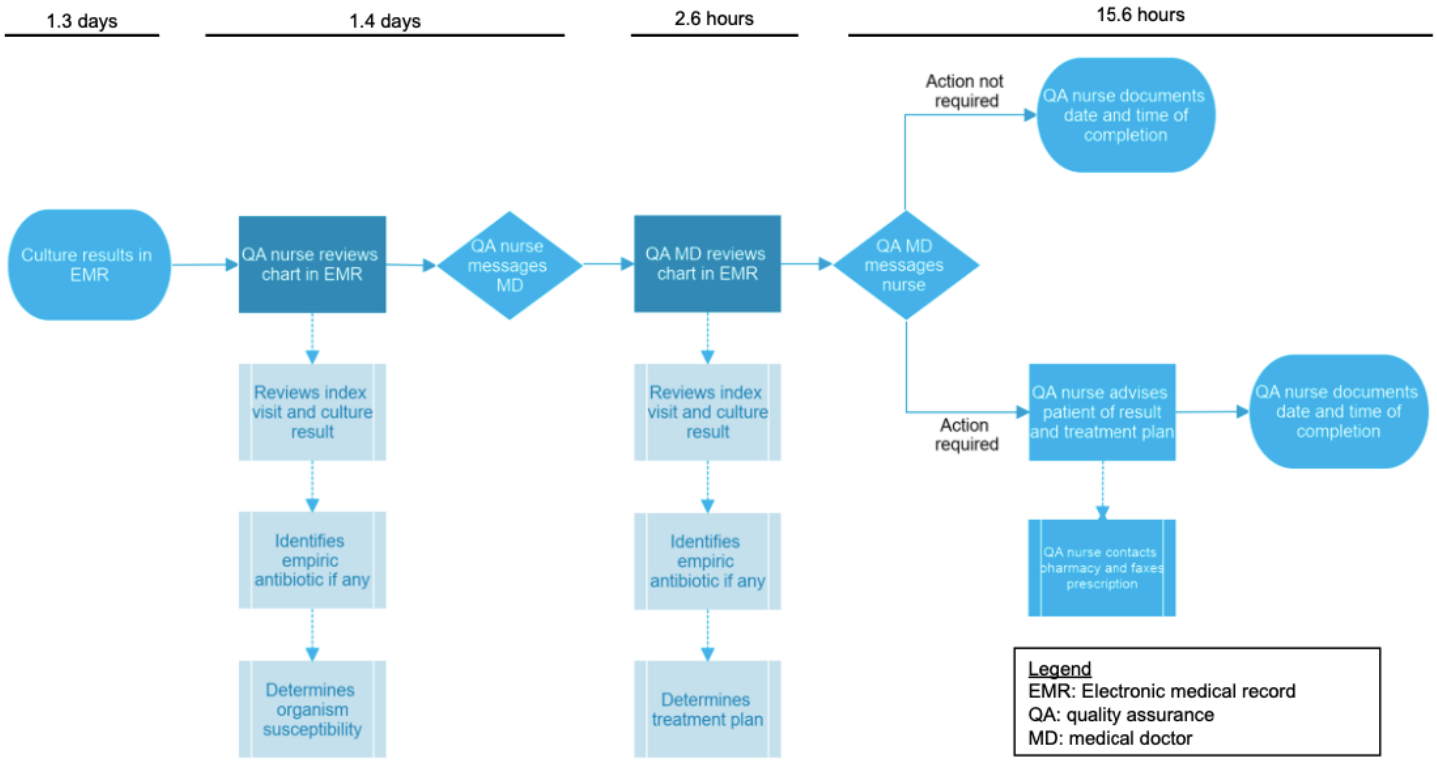

Figure 1. Current process for follow-up of urine culture results pending at discharge.

associated with assessed patient or microbiological factors. Table 1 reports the association between the time to action and assessed patient or microbiological factors.

The mean time between a nurse receiving instructions and patient follow-up was 15.6 hours (SD 23.6 hours). Overall, the mean number of days from ED discharge to follow-up completion was 3.4 days (SD 2.1 days). 98.4% (95% CI 91.8-99.7%; n=64) of patient follow-ups were documented. 71.9% (95% CI 59.9-81.4%; n=46) of these patients were successfully contacted on the first attempt, 23.4% (95% CI 14.8-35.1%; n=15) required a second attempt, and 4.7% (95% CI 1.6-12.9%; n=3) required three attempts.

Characteristics of types of physician action

Of the 65 patients initially identified as requiring culture follow-up, 34 required a change in antibiotic while 17 required an antibiotic (no empirical antibiotic was prescribed at discharge) or an additional antibiotic (add-on therapy). Six patients required clinical follow-up with a non-ED health-care provider. Two patients were asked to return to the ED for reassessment and both patients were successfully contacted on the first attempt. Two patients had culture results that did not require any action. For four patients, no physician action was documented.

DISCUSSION

In our study of the follow-up of positive urine culture results, the mean time from ED discharge to follow up of positive urine culture results was more than three days. We hypothesized that the longest stage in the follow-up process would be attributed to physician review given the various steps required, including opening the record, reviewing the index visit, and identifying an appropriate antibiotic if needed. However, this stage was the shortest in the process and was not associated with patient or microbiological factors. In contrast, a mean of 50 hours for those culture results requiring follow-up fell under the purview of the QA nurse.

While the overall time to urine culture follow-up in our study is likely context dependent, it differs considerably from those times reported in the literature. One study reported a mean pre-intervention culture follow-up time from laboratory report to family contact of just over 20 hours, while another reported a mean pre-intervention follow-up culture time from discharge to patient contact of 38 hours.[5,7] In our sample of patients, reducing the follow-up process to 20 hours would have saved over 4,000 hours cumulatively in-patient delay.

While it is difficult to assess if the times of the various stages in our follow-up process were clinically significant, we know that delays in treatment of organisms resistant to empiric antibiotics can result in adverse outcomes including upper urinary tract infections, bacteremia or sepsis, and ongoing symptoms, including pain.[1] Conversely, continuation of unneeded antibiotics contributes to antibiotic resistance, a problem with significant healthcare and economic costs.[8] As such, timely follow-up has the potential to improve patient and population outcomes.

LIMITATIONS

Our results should be interpreted with caution. We deliberately focused on urine cultures as opposed to broadly examining all microbiological samples to reduce heterogeneity. Coupled with small sample sizes and contextual differences, our results may not be generalizable to other types of cultures (e.g., blood, wound) or settings. For exploratory analyses, we did not include specific values (e.g., renal function, corrected QT interval) as they were not present for all included patients. We also did not assess the length of time taken to complete the individual physician and nursing actions (i.e., a time and motion analysis) for each step in the process (e.g., opening and reviewing the electronic chart, calling a patient) as this was beyond the scope of this work. For example, in addition to managing test result follow-up, QA nurses on multiple occasions must stop their QA work to support patient care in various areas. Consequently, the times calculated may not accurately reflect the true time taken. Our study also examined a period during the COVID-19 pandemic, a time when staffing shortages may have influenced nursing coverage and therefore, the work of the QA nurse.

FUTURE WORK

Following the review of these findings with our local departmental QI and patient safety (QIPS) committee, we uncovered several opportunities for improvement in addition to addressing the limitations previously described.

Locally, the longest stage in our QA process was from the availability of culture results to the transfer of results to the physician. For the nearly 40% of culture results not requiring further action, the mean delay to transfer of culture results to physicians for review was nearly 34 hours. To address this issue, our team is reviewing and refining the underlying rules of reports generated within the electronic medical record to eliminate results being inappropriately routed (i.e., not requiring follow-up) thereby improving the "signal" to "noise" ratio for QA nurses. Similarly, machine learning may be used to completely automate the identification and/or follow-up of benign culture results (e.g., cultures with no growth or where bacterial susceptibility matches the antibiotic prescribed at discharge), thereby reducing the amount of time spent by staff and the time delay.[9] While AI-based identification of pertinent findings requiring follow-up has been feasible in the context of radiology, specific algorithm development, validation, and external testing for microbiological follow-up is currently unknown.[10]

Nearly 30% of culture results that were followed up required more than one attempt for successful patient contact with significant variation in the time to follow-up. Anecdotally, nurses reported challenges identifying patients' pharmacies and delays in faxing prescriptions. Capturing this information in the electronic medical record (EMR) at triage may enhance downstream process efficiencies by supporting the completion of follow-up. For example, Burchett et al. describe the recording of patients' preferred pharmacy and the addition of an "e-prescribe" function as critical to the success of their intervention in reducing the time to urine culture follow-up.[7] In conjunction with our local information management group, we are exploring ways to collect and update pharmacy information including at registration, at triage, and through a connected patient portal (e.g., MyChart). An automated EMR report to identify and track issues causing delays in patient follow-up is also being developed and will be made available to QA nurses and physicians. Finally, trials are underway to align QA nursing shifts with times when culture results are received and assess the impact of a dedicated nurse practitioner responding to microbiological results.

CONCLUSION

Post-discharge follow-up of urine cultures ordered in the ED are important for ensuring appropriate antimicrobial exposure and timely care. In this exploratory retrospective chart review at a single centre, more than three days were required to complete follow-up for urine culture results identified post-discharge with most of the process overseen and completed by QA nurses. Compared with other institutions, there is a considerable delay in the follow-up process. Informatics-based interventions could yield significant reductions in time to urine culture follow-up and, potentially, workloads for nursing-led QA activities. In

addition to addressing the limitations of the present study, future work will examine the impact of these interventions on culture follow-up times.

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Table 1. Association between time to physician action and various patient and microbiological characteristics.

Characteristic	Details	p-value	Statistical test
Age at the time of discharge		0.62	Pearson Correlation Coefficient
Sex	Males: N=28; 136.1 min (2.3h) Females: N=37; 171.3 min (2.9h)	0.73	t-test
Residence (home or facility)	Facility: N=15; 221.4 min (3.7h) Home: N=50; 136.5 min (2.3h)	0.47	t-test
CTAS score for index visit	CTAS 2: N=17; 225.0 min (3.7h) CTAS 3: N=44; 139.3 min (2.3h) CTAS 4: N=4; 48.6 min (0.8h)	0.65	ANOVA
Presence of allergy to any antibiotic	Allergy: N=16; 124.6 min (2.1h) No allergy: N=49; 166.4 min (2.8h)	0.72	t-test
Presence of a Cr result in the last six months	Result: N=55; 155.6 min (2.6h) Unknown: N=10; 159.1 min (2.7h)	0.98	t-test
Presence of a QTC interval in the last six months	QTC: N=31; 204.3 min (3.4h) Unknown: N=34; 112.2 min (1.9h)	0.37	t-test
Number of organisms grown	1 organism: N=55; 182.5 min (3.0h) 2 organisms: N=9; 11.6 min (0.2h) 3 organisms: N=1; 4.9 min (0.1h)	0.46	ANOVA

Racial Discrimination During the COVID-19 Pandemic and Mental Health of Young Adults: A Cross-Sectional Study of University Students From East Asian Backgrounds

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Date Submitted: June 15, 2022
Date Accepted: July 18, 2022
Date Published: April 5, 2023

DOI: https://doi.org/10.18192/uojm.v13i01.6413

Keywords: *COVID-19, East Asians, xenophobia, racial discrimination, coping, mental health*

ABSTRACT

With the COVID-19 pandemic, there has been an increase in mental health problems in the population worldwide. During the pandemic, individuals from East Asian backgrounds have been blamed for COVID-19 and faced xenophobic attacks, leading to increased incidents of racial discrimination. We administered an online survey to examine (a) associations between in-person and online racial discrimination and mental health (i.e., anxiety and depression) among East Asian university students (n=169) in Canada and (b) the extent to which coping strategies and ethnic/cultural identity stage (e.g., exploration, resolution, affirmation) moderate the associations between discrimination and mental health. Results from hierarchical regressions indicated that experiencing online racial discrimination predicted more anxiety (b = .263, *SE* = .070, p < .001) and depression (b = .296, *SE* = .073, p < .001) symptoms. Using emotion-focused disengagement coping strategies predicted more anxiety (b = .705, *SE* = .129, p< .001) and depression (b = .763, *SE* = .127, p < .001). However, identity affirmation (i.e., positive feelings towards ethnic groups) predicted less depression (b = -.533, *SE* = .245, p = .031). Results suggest that exposure to online racial discrimination during the pandemic has a negative effect on East Asian students' well-being. However, positive feelings towards one's ethnic identity may protect against mental health problems related to experiences of racial discrimination.

RÉSUMÉ

Avec la pandémie de COVID-19, il y a eu une augmentation des problèmes de santé mentale dans la population mondiale. Au cours de la pandémie, les personnes d'origine est-asiatique ont été accusées d'être responsables du COVID-19 et ont fait l'objet d'attaques xénophobes, ce qui a entraîné une augmentation des incidents de discrimination raciale. Nous avons administré une enquête en ligne pour examiner (a) les associations entre la discrimination raciale en personne et en ligne et la santé mentale (c'est-à-dire l'anxiété et la dépression) chez les étudiants universitaires d'Asie de l'Est (n=169) au Canada et (b) la mesure dans laquelle les stratégies d'adaptation et le stade de l'identité ethnique/culturelle (par exemple, l'exploration, la résolution, l'affirmation) modèrent les associations entre la discrimination et la santé mentale. Les résultats des régressions hiérarchiques indiquent que l'expérience de la discrimination raciale en ligne prédit davantage de symptômes d'anxiété (b = .263, *SE* = .070, p < .001) et de dépression (b = .296, *SE* = .073, p < .001). L'utilisation de stratégies de désengagement axées sur les émotions permettait de prédire une plus grande anxiété (b = .705, *SE* = .129, p < .001) et une plus grande dépression (b = .763, *SE* = .127, p < .001). Cependant, l'affirmation d'identité (c'est-à-dire les sentiments positifs envers les groupes ethniques) prédisait moins de dépression (b = -.533, *SE* = .245, p = .031). Les résultats suggèrent que l'exposition à la discrimination raciale en ligne pendant la pandémie a un effet négatif sur le bien-être des étudiants est-asiatiques. Cependant, des sentiments positifs envers l'identité ethnique d'une personne peuvent la protéger contre les problèmes de santé mentale liés aux expériences de discrimination raciale.

The coronavirus 2019 (COVID-19) pandemic has resulted in significant declines in physical and mental health among people worldwide.[1–10] The World Health Organization reported a 25% global increase in the prevalence of anxiety and depression in the first year of COVID-19.[10] Students and people from disadvantaged backgrounds have been negatively affected since the beginning of COVID-19 in several ways, including job loss, remote learning, and experiencing discrimination.[11] Racialized groups, particularly those from Asian backgrounds, reported experiencing higher rates of racial discrimination.[12–18] In Canada, individuals from East and Southeast Asian backgrounds reported experiencing a 19-30% increase in racial discrimination during COVID-19.[19] Given the well-established impact of racial discrimination on mental health, racial discrimination related to COVID-19 poses a risk to the mental health of individuals from Asian backgrounds.[14,20–23] In the present study, we investigated associations between racial discrimination and mental health among East Asian university students in Canada in the context of COVID-19. We also examined the extent to which students' coping strategies and their ethnic identity (EI) played a role in moderating the relationship between racial discrimination and mental health outcomes.

University students from Asian backgrounds, who are often immigrants or international students, manage a multitude of stressors, including acculturative stress and discrimination, as well as multiple cultural identities exploration.[24–28] While acculturating to Canadian society, many young adults are in the process of exploring mainstream and heritage cultural identities, which can go through the stages of exploration, resolution, and affirmation.[29,30] Exploration encompasses the aspect of seeking out information about one's ethnic/racial group; the resolution is the extent to which one has decided what their group membership means to them, and affirmation is the development of positive feelings about one's group.[30] Exploration and resolution provide an important foundation for developing affirmation and a sense of belonging to one's cultural group or identity.[31] As identity processes continue to develop into young adulthood, these stages may play a role in Asian students' well-being, which can either buffer against, or exacerbate, adjustment and well-being difficulties.[32] For example, affirmation may protect individuals due to the focus on positive aspects of their group membership.[27,33] Conversely, individuals who are still in the stage of identity exploration may be vulnerable to the effects of xenophobia towards their ethnic group and impacts progress to the following two stages.[34] In the context of COVID-19-related racial discrimination, the ethnic identity stage may play a key role in Asian students' well-being.

During the pandemic, people coped with COVID-19-related stressors (e.g., school closures, working from home, and being fearful of or experiencing COVID-19-related discrimination) using multiple strategies.[1,6,35–37] Coping strategies are cognitive or behavioural efforts used to combat stressors experienced in daily life which can be categorized as problem-focused (i.e., managing the cause of the stressor) or emotion-focused (i.e., managing the emotional response to the stressor).[38,39] These strategies can be further categorized as engagement strategies, which are actions taken to confront a stressor, or disengagement strategies, which are actions taken to avoid a stressor or the emotions related to it. Disengagement strategies have long been considered less effective for dealing with stressors.[40,41] However, more recent literature has provided evidence that some disengagement strategies, such as positive distraction, can be adaptive in managing stressors.[42] Additionally, cultural values can play an important role in how people approach and interpret stressors, thereby affecting what coping strategies will be useful.[39,43] On one hand, engagement strategies (e.g., social support) have been suggested to be effective because they can help manage the stressor directly and its related emotions, which can protect individuals from experiencing distress later on.[37,44,45] On the other hand, certain disengagement strategies (e.g., positive avoidance) may also be effective for other individuals depending on their accordance with collectivistic cultural values, such as behaviours to maintain group harmony.[37,44,46]

The purpose of this study was to examine the extent to which (1) in-person and online racial discrimination are associated with mental health symptoms (i.e., depression, anxiety) among East Asian university students in Canada; and (2) coping strategies (e.g., problem-focused or emotion-focused and engagement or disengagement) and ethnic identity moderate the association between racial discrimination and mental health. We hypothesized racial discrimination would negatively affect the mental health of university students from East Asian backgrounds (i.e., Chinese, Japanese, and Korean backgrounds). Further, we

hypothesized that students who used either engagement problem-focused or engagement emotion-focused coping strategies would report lower levels of depression and anxiety.

METHODS

This was a cross-sectional survey created on Qualtrics and accessible to participants via a link and QR code. We recruited participants from Canadian urban-centred universities within densely populated metropolitan areas and pursued a large sample size to reduce sample bias. Participants were recruited from September 2021 until March 2022 from social media, student associations, classes, and student participant pools. The study was advertised to current university students across social media platforms (i.e., Instagram, Facebook, Twitter), including student associations of specific ethnic/cultural groups.

Data for this study were analysed from participants who self-identified as East Asian (i.e., Chinese, Korean, Japanese, Taiwanese descent). This study was approved by the University of Ottawa Research Ethics Board (#: H-06-21-7101). Participants were presented with a consent form prior to the first page of the survey. After survey completion, they were provided with class credit or the chance to win one of 20 $50 Visa gift cards.

Measures

Demographic Questionnaire

Participants completed a standard demographics questionnaire,[47-48] which included questions about age, gender, ethnic background, and country of birth.

Predictors

In-person discrimination was assessed with the *Everyday Discrimination Scale*,[49] which includes 9 items rated on a 4-point Likert-type scale (0 = never to 3 = often). Online racism was measured with the *Perceived Online Racism Scale – Very Brief* (PORS-VB).[50] Participants rated how often they had experienced online racism in the past six months for 6 items rated on a 5-point Likert-type scale (1 = never to 5 = always).

Outcomes

Anxiety was assessed using the *Generalized Anxiety Disorder* scale (GAD-7).[51] The 7 items are scored on a 4-point Likert-type scale (0 = not at all to 3 = nearly every day). Depression was assessed using the *Centre for Epidemiological Studies Depression Scale* (CES-D).[52] This measure asked how participants felt in the past week with 10 items rated on a 4-point Likert-type scale (0 = rarely or none of the time/less than 1 day to 3 = most or all of the time/5-7 days).

Moderators

Three stages of EI (exploration, resolution, affirmation) were assessed using the *Ethnic Identity Scale-Brief* (EIS-B).[30] This scale is composed of 9 items rated on a 4-point Likert-type scale (1 = does not describe me at all to 4 = describes me very well), with 3 items assessing each stage. The *Coping Strategies Inventory Short Form* (CSI-SF) (16 items) was used to examine 4 types of coping strategies: problem-focused engagement, problem-focused disengagement, emotion-focused engagement, and emotion-focused disengagement.[39] Each subscale is composed of 4 items, with each item rated on a 5-point Likert-type scale corresponding to the time spent using that strategy (1 = never to 5 = almost always).

Sample

A G*Power a priori power analysis was conducted for multiple regression analysis, revealing that for a small effect size of .02, 80% power, and an alpha level of .05, the minimum sample size would be 111 participants.[53]

Analytical Plan

Data were analyzed using IBM SPSS v.28 statistical software. Invalid responses (e.g., failing to correctly answer the attention check question and an incompletion of the survey) were excluded. Univariate analyses were conducted to provide descriptive statistics. Proportions and chi-squared tests were used to describe the demographic characteristics of the sample (e.g., gender, immigrant status). Pearson's correlations were calculated for continuous variables to examine associations between coping, racial discrimination, and mental health scales.

Means and standard deviations (e.g., one-sample t-tests) were used for continuous variables (e.g., discrimination and mental health scales). Hierarchical multiple regressions were conducted to examine study objective 2, the extent to which ethnic identity and coping strategies moderated the association between racial discrimination and the two mental health outcomes. Categorical predictors were dummy coded (e.g., gender, born in Canada), and continuous predictors were mean-centered before conducting the multiple regressions. Step 1 included demographic characteristics, Step 2 included in-person and online racial discrimination, and Step 3 included coping strategies and EI.

RESULTS

Descriptive and Correlational Analyses

Descriptive characteristics for the study variables are presented in Table 1. T-tests were conducted to examine differences across gender (Table 2) and immigration status (Table 3) on the racial discrimination, moderator, and outcome measures. Foreign-born students reported lower levels of online racial discrimination ($t(167) = -3.89$, $p < .001$), and female students reported using problem-focused engagement coping strategies more than males ($t(167) = -3.70$, $p < .001$). No other significant differences were observed across variables by gender or immigrant status characteristics. Pearson correlations among the measures are presented in Table 4. Anxiety and depression were each found to be positively related to experiences of online discrimination (Anxiety $r = 0.27$, $p < .001$; Depression $r = 0.29$, $p < .001$) and emotion-focused disengagement (EFD) coping (Anxiety $r = 0.44$, $p < .001$; Depression $r = 0.47$, $p < .001$). The CES-D scale reliability was $\alpha = 0.79$, the GAD scale reliability was $\alpha = 0.70$, and the CSI-SF scale reliability was $\alpha = 0.70$.

Hierarchical Regression

Three-step hierarchical regression models were conducted to examine if online or in-person discrimination predicted mental health symptoms and whether coping strategies and EI stages moderated the associations between discrimination and mental health (Table 4, 5).

Step 1 included demographic characteristics, step 2 included online and in-person racial discrimination, and step 3 included the four coping strategies and three EI stages. Results are presented separately for anxiety and depression.

Anxiety Model

Results indicated no significant effects for gender and immigrant status. Experiencing higher levels of online discrimination predicted more anxiety symptoms in step 2 ($B = .263$, $SE = .070$, $p < .001$). Using EFD coping strategies predicted more anxiety symptoms over and above demographic and discrimination measures ($B = .705$, $SE = .129$, $p < .001$). In the third step, online discrimination was still a significant predictor of anxiety ($B = .170$, $SE = .068$, $p < .05$). No other statistically significant effects were observed.

Depression Model

Similar to the anxiety model, the first step of the depression model was non-significant. In the second step, experiencing online discrimination predicted more depression symptoms ($B = .296$. $SE = .073$, $p < .001$). Emotion-focused coping strategies predicted more depression symptoms after controlling for demographic and discrimination measures ($B = .705$, $SE = .129$, $p < .001$). In step 3, results indicated that participants who were in the affirmation stage of their ethnic identity development experienced lower levels of depression over and above demographic and discrimination measures ($B = -.533$, $SE = .245$, $p < .05$). Online discrimination remained significant in the third step ($B = .165$, $SE = .067$, $p < .05$).

DISCUSSION

Although a large number of post-secondary students from East Asian backgrounds study in Canada, the literature examining the experiences and mental health of this population has been lacking.[54] This study aimed to examine if racial discrimination experienced by students from East Asian backgrounds impacted their mental health outcomes during COVID-19 while considering the possible moderating variables of coping strategies and ethnic identity. Our findings are consistent with previous literature on the association between racial discrimination and mental health, including publications concerning the COVID-19 pandemic.[12–17,55,56] The results of our study indicated that Canadian-born East Asian university students were more

likely to experience online racial discrimination than foreign-born students during the COVID-19 pandemic and that these experiences predicted higher levels of depression and anxiety symptoms for all students. Our results add to the literature by considering variables that may moderate this association for university students from East Asian backgrounds in Canada.

However, more recent literature has provided evidence that some disengagement strategies, such as positive distraction, can be adaptive in managing stressors. Due to COVID-19 lockdowns, university students were less likely to have direct, in-person contact with others in the community, which can explain the lower levels of in-person racial discrimination found in our study.[57] In contrast, online interactions and time spent on social media increased during the pandemic, and instances of racial discrimination could easily be targeted directly at them or observed happening to people from the same cultural background.[58] The online discrimination questionnaire used in our study (PORS-VB) measures experiences directed at the individual in addition to incidents experienced by, or reported about, other people observed online, whereas the *Everyday Discrimination Scale* assesses discrimination targeted at the individual themselves.[49,50] Therefore, the broader criteria of PORS-VB may underlie the greater number of reported online experiences by participants.

In our study, Canadian-born participants experienced more online racial discrimination than foreign-born participants. Past literature examining racial discrimination has provided mixed results, with some studies finding American-born participants from Asian backgrounds experiencing more racial discrimination than foreign-born participants as well as studies finding the opposite.[59–64] It is important to note these previous studies examined general racial discrimination and did not specify across contexts (e.g., in person, in academic settings, on social media platforms). Our study contributes to the literature as we examined general discrimination using the *Everyday Discrimination Scale* as well as examining racial discrimination in online contexts with the PORS-VB measure.[49,50] One explanation for our significant finding of online racial discrimination impacting mental health outcomes could be the quarantining protocols and social distancing policies in place at the time of our survey. This may have resulted in Canadians spending an increased amount of time at home and online, leading to increased exposure to and significance in online discrimination.[58] Further, the difference based on immigration status may be due to Canadian-born immigrants having increased opportunities for social contact with members of mainstream society across different contexts.[58,61,65] They may be more likely to come in contact with individuals who express negative attitudes towards their ethnic group, such as on North American social media platforms, which are more likely to be used by Canadian-born immigrants than foreign-born immigrants.[61,65,66] The COVID-19 pandemic presented a situation where many individuals spent increased amounts of time online, including school, work, and social media.[58] In-person interactions were often avoided during the pandemic, whereas news and messages online were not as easily avoidable, which can have a detrimental impact on one's mental health.

The exploration and resolution stages of EI were not significantly associated with anxiety or depression, nor did they moderate the association between racial discrimination and mental health outcomes. The affirmation stage of EI predicted less depression in this study. This finding is consistent with past literature suggesting affirmation has a protective effect against depression.[27,30,67–69] Affirmation, sometimes referred to as private regard, is the development of positive affect toward the group.[29] Social environments play an important role in EI development.[70] An individual's identity develops, in part, due to the dynamic interactions between the individual and social context. Experiences of discrimination can lead to questioning one's identity. However, if an individual's identity is well-developed with high affirmation, their mental health may not be as negatively impacted if they experience discrimination.[70] When an individual has clear positive feelings towards their ethnic group and group members, others' negative beliefs and actions towards the group are less likely to impact an individual's affective response. This was observed in our study, where positive feelings about East Asian individuals had a buffering response to the depression predicted by experiencing online discrimination.

Finally, we found that participants used each coping strategy to a similar degree. Consistent with past literature, both forms of disengagement coping were positively correlated with anxiety and depression.[71,72] Emotion-focused disengagement coping can include strategies such as not seeking social support and ignoring a stressor. While avoiding thoughts and environments surrounding

discrimination can be helpful, this avoidance may become more maladaptive if the stressors are difficult to avoid. For example, avoidance of online media platforms and news may be beneficial in the short term to avoid potential experiences of racial discrimination; however, disengagement is not sustainable in the long term and could potentially lead to maladaptive outcomes.

Limitations

This study included several limitations. First, we recruited a convenience sample limiting the generalizability of our results beyond university students. Future research would benefit from a larger population-based sample size with diverse immigration characteristics across Canada. While this study might have possible non-response biases, we attempted to minimize this limitation using a variety of techniques. First, an incentive, entering to win a Visa gift card, was provided after survey completion.[73] Additionally, questions were randomized, and the scales used were well-validated and included reverse-scored items.[74] Further, attention check items were included throughout the survey to encourage motivated responses. Due to the sensitive content of the survey, participants were also provided with the option to skip questions.[75] Next, given that the *Everyday Discrimination Scale* measures general day-to-day discrimination and not racial discrimination specifically (e.g., "You are called names or insulted"), participants may also have considered other forms of discrimination (e.g., gender discrimination) in their responses.[49] Additionally, unlike the PORS-VB, this measure does not specify the context of the participants' experiences, which may mean participants considered experiences of discrimination across all contexts, including online platforms.

Conclusion

Our study adds to the Canadian literature on the experiences of East Asian Canadians' experiences of racial discrimination and their impact on mental health during the COVID-19 pandemic. Our findings also supported the importance of personal and cultural processes in moderating the association between discrimination and mental health (i.e., coping strategies, mental health). Given the increased experiences of racial discrimination and ethnic-based harassment during the COVID-19 pandemic, it is important to comprehend how the association between experiencing racial discrimination and mental health outcomes is influenced by immigration status, ethnic identity, and other personal characteristics. Future studies would benefit from reporting experiences of racial discrimination across specific contexts (e.g., social media platforms, academic settings) to further investigate how these experiences may impact mental health outcomes.

Conflicts of Interest

There are no conflicts of interest for this project.

Funding

Funding for this study is provided by the Seed Funding Opportunity (SFO) awarded to Irene Vitoroulis, Ph.D., by the faculty of Social Sciences at the University of Ottawa.

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Table 1. Demographic Characteristics of Participants (n=169)

Variable		n	%	*M*	*SD*	Range	α
Gender	Female	119	70.4				
	Male	50	29.6				
Age				19.63	1.41	17-24	
Born in Canada	Yes	52	30.8				
	No	117	69.2				
In-person Discrimination		169	100.0	15.9	7.0	8-36	
Online Discrimination		156[a]	92.3	15.8	6.2	6-30	
EI Exploration				7.5	2.7	2-12	0.80
EI Resolution				9.9	2.3	3-12	0.89
EI Affirmation				11.0	1.7	4-20	0.77
EFE				12.4	3.4	4-20	0.71
EFD				13.7	3.1	4-20	0.70
PFE				12.9	3.4	4-20	0.80
PFD				13.1	3.8	7-20	0.70

Note. [a]Participants who experienced online discrimination; n=3 skipped the POR-VS measure, n = 11 recorded a score of 6 indicating never experienced online discrimination. EFE = Emotion-focused Engagement, PFE = Problem-focused Engagement, PFD = Problem-focused Disengagement, EFD = Emotion-focused Disengagement

Table 2. t-tests Examining Gender Differences across Dependent Variables

Variable	Female		Male		t(169)	p	Cohen's d
	M	*SD*	*M*	*SD*			
In-person Discrimination	16.09	7.13	15.40	6.64	0.59	0.56	6.99
Online Discrimination	15.73	6.16	16.04	6.43	t(167) =-0.29	0.77	6.24
Anxiety	9.91	5.80	8.40	4.73	1.63	0.11	5.51
Depression	12.31	5.68	11.44	5.96	0.89	0.37	5.76
EI Exploration	7.56	2.74	7.44	2.63	-0.27	0.79	2.71
EI Resolution	9.90	2.28	9.74	2.21	-0.44	0.66	2.26
EI Affirmation	10.95	1.67	11.00	1.67	0.18	0.86	1.66
EFE Coping	12.42	3.73	12.32	2.63	-0.17	0.86	3.44
PFE Coping	13.52	3.31	11.42	3.50	-3.70	<.001	3.37
PFD Coping	13.36	2.82	12.74	2.60	-1.34	0.18	2.75
EFD Coping	13.67	2.96	13.62	3.46	-0.10	0.92	3.12

Note. EI = Ethnic Identity, EFE = Emotion-focused Engagement, PFE = Problem-focused Engagement, PFD = Problem-focused Disengagement, EFD = Emotion-focused Disengagement

Table 3. t-tests Examining Immigration Status Differences across Dependent Variables

Variable	Foreign-born		Canadian-born		t(169)	p	Cohen's d
	M	SD	*M*	SD			
In-person Discrimination	16.01	7.37	15.60	6.03	0.36	0.72	6.99
Online Discrimination	14.62	6.01	18.48	5.89	t(167) = -3.89	<.001	5.98
Anxiety	9.40	5.42	9.60	5.83	-0.21	0.83	5.54
EI Exploration	7.68	2.67	7.17	2.76	1.14	0.26	2.70
EI Resolution	9.91	2.32	9.73	2.11	0.49	0.63	2.26
EI Affirmation	11.05	1.62	10.77	1.72	1.03	0.31	1.65
EFE Coping	12.24	3.64	12.73	2.92	-0.86	0.39	3.44
PFE Coping	12.88	3.67	12.94	3.08	-0.11	0.92	3.50
PFD Coping	13.17	2.88	13.17	2.50	-1.34	0.99	2.77
EFD Coping	13.44	3.27	14.13	2.66	0.01	0.18	3.10

Note. EI = Ethnic Identity, EFE = Emotion-focused Engagement, PFE = Problem-focused Engagement, PFD = Problem-focused Disengagement, EFD = Emotion-focused Disengagement

Table 4. Correlations Examining Associations Across Study Variables

Variable	*M*	*SD*	1	2	3	4	5	6	7	8	9	10	11
1. Anxiety	9.46	5.53	--										
2. Depression	12.05	5.76	.66***	--									
3. In-person D	15.89	6.79	.00	.04	--								
4. Online D	15.83	6.22	.27***	.29***	.11	--							
5. EI Exploration	7.53	2.70	-.13	-.19	.08	-.02	--						
6. EI Resolution	9.86	2.26	-.12	-.11	-.04	.06	.42***	--					
7. EI Affirmation	10.96	1.65	-.12	-.22	-.14	-.22	.08	.27***	--				
8. EFE Coping	12.39	3.43	.17*	.18	-.03	.17	.01	-.03	-.14	--			
9. PFE Coping	13.66	3.11	-.05	-.13	-.06	-.02	.14	.14	.05	.33***	--		
10. PFD Coping	12.90	3.49	-.20**	-.26***	-.16-	-.18	.19*	.34***	.24**	-.07	.29***	--	
11. EFD Coping	13.18	2.76	.44***	.47***	-.10	.18	-.11	-.05	.05	.19*	-.10	-.03	--

Note. *** p < .001, ** p < .01, * p < .05 EI = Ethnic Identity, EFE = Emotion-focused Engagement, PFE = Problem-focused Engagement, PFD = Problem-focused Disengagement, EFD = Emotion-focused Disengagement

Table 5. Hierarchical Regression Analysis for Anxiety

N	B	*SE*	95% CI		p
			LL	UL	
Step 1					
Age	-.279	.337	-.944	.386	.409
Gender	1.348	.949	-.525	3.221	.157
Immigration Status	-.042	1.000	-2.016	1.933	.967
R^2 change	.020				
Step 2					
In-person Discrimination	-.028	.060	-.146	.090	.683
Online Discrimination	.263***	.070	.125	.400	<.001
R^2 change	.099				
Step 3					
EI Exploration	-.075	.155	-.382	.232	.628
EI Resolution	-.145	.200	-.539	.249	.469
EI Affirmation	-.181	.248	-.671	.309	.467
EFE Coping	.060	.123	-.184	.303	.630
PFE Coping	-.002	.127	-.253	.250	.990
PFD Coping	-.234	.157	-.545	.076	.138
EFD Coping	.705***	.129	.451	.959	<.001
R^2 change	.296				

Note. *** p < .001. EI = Ethnic Identity, EFE = Emotion-focused Engagement, PFE = Problem-focused Engagement, PFD = Problem-focused Disengagement, EFD = Emotion-focused Disengagement

Table 6. Hierarchical Regression Analysis for Depression

N	B	*SE*	95% CI		p
			LL	UL	
Step 1					
Age	-.218	.353	-.916	.479	.537
Gender	.760	.994	-1.203	2.723	.446
Immigration Status	-.389	1.048	-2.458	1.680	.711
R^2 change	.007				
Step 2					
In-person Discrimination	-.002	.062	-.125	.121	.973
Online Discrimination	.296***	.073	.153	.440	<.001
R^2 change	.102				
Step 3					
EI Exploration	-.256	.154	-.560	.048	.098
EI Resolution	.074	.197	-.316	.463	.710
EI Affirmation	-.533*	.245	-1.018	-.049	.031
EFE Coping	.125	.122	-.115	.366	.306
PFE Coping	-.136	.126	-.384	.113	.283
PFD Coping	-.268	.155	-.575	.039	.087
EFD Coping	.763***	.127	.512	1.014	<.001
R^2 change	.365				

Note. * $p < .05$, *** $p < .001$. EI = Ethnic Identity, EFE = Emotion-focused Engagement, PFE = Problem-focused Engagement, PFD = Problem-focused Disengagement, EFD = Emotion-focused Disengagement

SUPPLEMENTARY INFORMATION

Racial Discrimination During the COVID-19 Pandemic and Mental Health of Young Adults: A Cross-Sectional Study of University Students From East Asian Backgrounds

DOI for the original publication: https://doi.org/10.18192/uojm.v13i01.6413

Administrative Infomation

1. Racial Discrimination During the COVID-19 Pandemic and Mental Health of Young Adults: A Cross-Sectional Study of University Students From Asian Backgrounds
2. Trial registration: Not applicable
3. Protocol version: Not applicable
4. Seed Funding Opportunity (SFO) awarded by the Faculty of Social Sciences
5. Roles and Responsibilities
   a. Names, Affiliations, and roles
      i. [1,2]Cloudia Rodriguez, B.A., Student Researcher
      ii. [1]Ruo Ying Feng, B.A., Student Researcher
      iii. [1]Zoe Campbell, B.A., Research Assistant
      iv. [1]Marilou Poitras, B.A., Research Assistant
      v. [1]Irene Vitoroulis, Ph.D., Assistant Professor

   Cloudia Rodriguez and Dr. Vitoroulis conceived the study and wrote all sections of the manuscript. All team members helped collect the measures. Zoe Campbell and Marilou Poitras uploaded the measures into Qualtrics. Ruo Ying Feng, Cloudia Rodriguez and Dr. Vitoroulis are responsible for database management and statistical analyses.

   [1]School of Psychology, University of Ottawa

   [2]Interdisciplinary School of Health Sciences, University of Ottawa

   b. Not applicable
   c. Not applicable
   d. Not applicable

Introduction

6. Background and Rationale
   a. With the Coronavirus (COVID-19) originating from Wuhan, China there has been an increase in racial discrimination towards Asians worldwide and specifically evident in North America.[1–6] Experiencing discrimination and fear of possibly experiencing it can harm the mental health of individuals.[7–10] Additionally, there has been an overall decline of individuals' mental health worldwide.[11–15] In the Canadian context, individuals from Asian backgrounds experience the process of acculturation, with different levels of acculturation impacting coping strategies utilized to face stressors.[16,17] For university students from Asian backgrounds, their usual stressors, in addition to COVID-19-related stressors, and fear of experiencing discrimination can negatively impact their mental health.[3,11,13,18] Few studies since the beginning of the COVID-19 pandemic have examined the experiences of discrimination and mental health of Asian university students in Canada and their utilized coping orientation. Therefore, this study will provide valuable data to support the subpopulations whose health has been negatively affected during the pandemic.
   b. Explanation of choice of comparators: Not applicable

7. We hypothesize that racial discrimination would have a negative impact on the mental health of university students from Asian backgrounds (specifically Chinese, Japanese, and Korean backgrounds). We also hypothesize students who use adaptive coping orientation such as active coping and positive reframing, will report lower levels of depression and anxiety. We expect those who report high levels of acculturation to Canadian culture and strong cultural identity to experience less racial discrimination and lower levels of depression and anxiety compared to those who are less acculturated to Canadian culture or who do not identify strongly with their heritage culture. We also expect individuals who experience mental health issues to participate in less physical activity.
   The purpose of the current study is to examine (1) the extent to which racial discrimination contributes to mental health problems (depression, anxiety) among university students from Asian backgrounds; (2) The coping orientation utilized and level of physical activity engaged in by university students from Asian backgrounds during COVID-19; and (3) the extent to which processes relevant to immigration, such as acculturation and cultural identity, moderate the relationship between racial discrimination and mental health.
8. Cross-sectional, survey design

Methods: Participants, Interventions, Outcomes

9. Online survey accessible through a link or QR code
10. Inclusion criteria: University students between 17-24 years old from Asian backgrounds.
11. Interventions: Not applicable
12. Primary Outcome Measures
    a. Assess levels of generalized anxiety with the *Generalized Anxiety Disorder Screener* (GAD-7).[19] The 7 items are scored on a 4-point Likert-type scale (0 = not at all, 1 = several days, 2 = more than half of days, 3 = nearly every day). A maximum score of 21 indicates very high anxiety symptoms and a minimum score of 0 indicated very low/no anxiety symptoms.
    b. Assess levels of depression with the *Centre for Epidemiological Studies Depression Scale* (CES-D).[20] This measure asks how participants have felt in the past week with 10 items rated on a 4-point Likert-type scale (0 = rarely or none of the time (less than 1 day), 1 = some or a little of the time (1-2 days), 2 = occasionally or a moderate amount of time (3-4 days), 3 = most or all of the time (5-7 days)). A maximum score of 30 indicates very high depression symptoms and a minimum score of 0 indicates very low/no depression symptoms.

13.1 Participant Timeline: Participants will be invited to participate in the study in the recruitment poster. As soon as recruitment opens in September until the project is terminated, participants will be able to access and complete the survey in one sitting, during their own time. There are 11 questionnaires pertaining to this study on this survey. There is no follow-up. When the survey is complete, participants may enter a draw to win 1 of 20 Visa gift cards (each worth $50).

13.2 Assessments Performed (Questionnaires)
   a. Socio-demographics (21 items)[21,22]
   b. Everyday Discrimination Scale (9 items)[23]
   c. Perceived Online Racism Scale – Very Brief (PORS-VB) (6 items)[24]
   d. Ethnic Identity Scale-Brief (EIS-B) (9 items)[25]
   e. Vancouver Index of Acculturation (VIA) (20 items)[26]
   f. Coping Strategies Inventory Short Form (CSI-SF) (16 items)[27]
   g. COVID-19 Family Stressor Scale (16 items)[28]
   h. Leisure Time Exercise Questionnaire (4 items)[29]
   i. Questions for Work Sitting and Breaks in Sitting Time (6 items)[30]
   j. Generalized Anxiety Disorder Screener (GAD-7) (7 items)[31]
   k. Centre for Epidemiological Studies Depression Scale (CES-D) (10 items)[32]

13.3 Schematic Diagram (Fig 1)

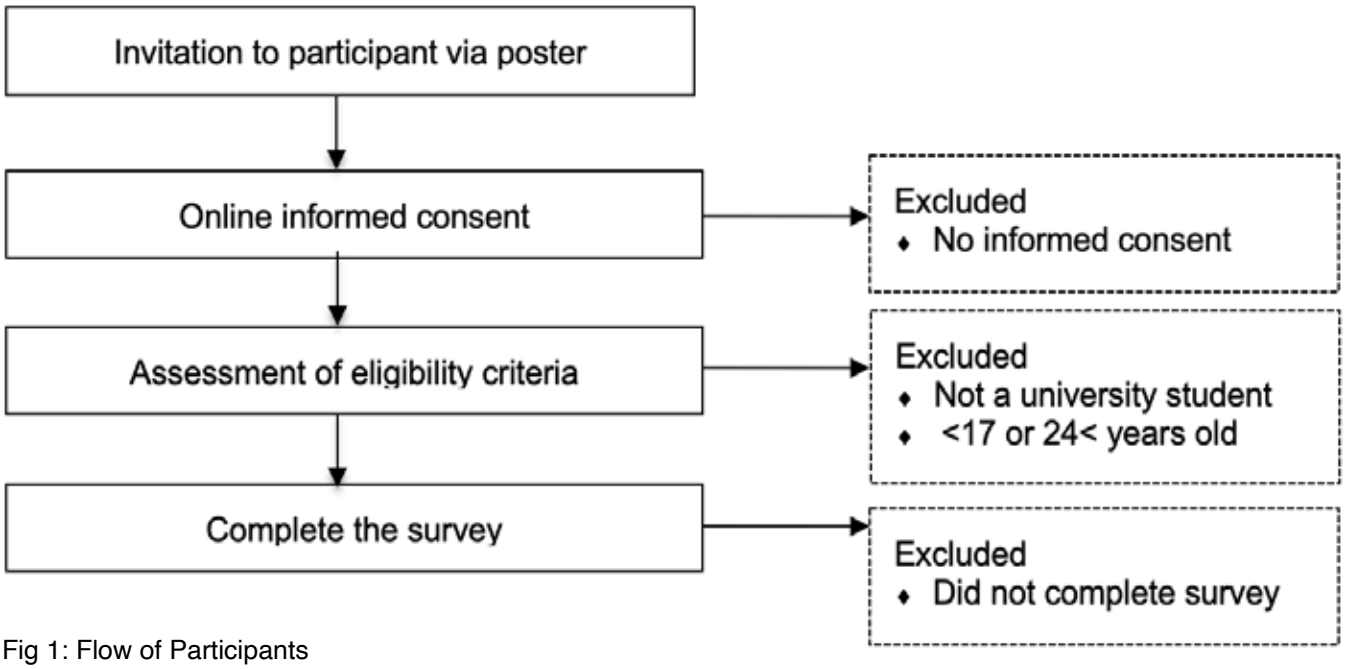

Fig 1: Flow of Participants

14. A minimum of 108 participants will be recruited to obtain adequate power for regression analyses.
15. Participants will be recruited starting August 2021 from classes and student associations. Professors of large classes will be contacted via email with the request to advertise our study as an announcement on Brightspace regarding the study recruitment and online survey. Student associations at the university will be contacted via email with the request to send our recruitment information and the online survey to the students on their mailing lists and via their social media. Poster advertisements will also be posted by the CDYD lab on social media and in university focused student groups.

Methods: Assignment of Interventions

16. All participants will complete the same questionnaires.
17. Not applicable

Methods: Data Collection, Management, and Analysis

18. Data Collection Methods
    a. The study will be conducted online, using Qualtrics. Participants will be invited to complete a 45-60 minute survey via a provided link or QR code on our poster. The QR code will send participants to the study webpage. The consent form will be presented first, followed by the survey questions.
    b. Plans to promote participant retention and complete follow-up: Not applicable. There is no follow-up for the study.
19. Data Management: All data will be saved on uOttawa servers and the data will not be shared with collaborating institutions. Upon completion of the study, all data will be screened to ensure quality and invalid responses (e.g., failing to correctly answer attention check questions) will be excluded.
    Data from the study will be collected and stored by Qualtrics and managed by Qualtrics data security policies. Data are encrypted and anonymized within this system. Upon study completion, data will be downloaded from Qualtrics, and all data will be removed from the online system. Data will then be stored in an encrypted, external hard drive owned and stored securely by Dr. Irene Vitoroulis, as well as password-protected computers that are stored in locked offices with restricted access.

20. Statistical Methods: The purpose of the current study is to examine (1) the extent to which online and in-person racial discrimination is associated with mental health problems (depression, anxiety) among university students from Asian backgrounds; (2) the extent to which coping orientation and level of physical activity during the COVID-19 pandemic are associated with levels of mental health; and (3) the extent to which processes relevant to immigration, such as acculturation and cultural identity, moderate the relationship between racial discrimination and mental health. Objective 1 will be addressed using descriptive analyses (mean levels, chi-square) to examine mean levels of online and in-person discrimination experiences among participants, including gender differences with sex an immigrant status. Objectives 2 and 3 will be addressed using hierarchical multiple regressions to examine the extent to which coping orientation and physical activity levels are associated with depression and anxiety and the extent to which acculturation and cultural identity moderate these associations.
    b. Not applicable
    c. Not applicable

Methods: Monitoring

21. Data Monitoring
    a. A Data Monitoring Committee has not been established as it is not needed. This decision was made as survey data are being collected and no interventions are being assigned.
    b. Dr. Irene Vitoroulis will make the final decision to terminate the trial. There will be no interim analyses conducted.
22. Possible harm: Psychological or emotional discomfort (e.g., anxiety, loss of confidence, regret for disclosing personal information).
23. Auditing: Not applicable

Ethics and Dissemination

24. This project has received ethics approval from the University of Ottawa REB. Ethics file number: H-06-21-7101
25. Protocol amendments: Not applicable
26. Consent
    a. A consent form is presented to the participant on the first page of the survey for interested participants to read and print for their records (Appendix A).
    b. Not applicable
27. The only directly identifiable information we will be collecting is an email address. We will require the participants' university email to enter the draw for participant remuneration. For those who win one of the 20 gift cards, we will use their email address to purchase and send their gift card.
    Data will be collected using Qualtrics. During the data collection period, data will be stored in Qualtrics and managed by Qualtrics data security policies. Data are encrypted and anonymized within this system. After responses are downloaded from Qualtrics, they will be removed from the online system and stored on password-protected computers that are stored in locked offices with restricted access. All data are de-identified.
28. No conflict of interest
29. Dr. Vitoroulis and Ruo Ying Feng will have access to the data, with Cloudia Rodriguez being granted access for analyses.
30. Not applicable
31. Dissemination Policy
    a. Results of the study will be published in UOJM and can later be submitted for internal or external conference presentations or other journals, recognizing UOJM was the primary publisher.
    b. No intended use for professional writers.
    c. Data will not be shared

Appendices

32. Consent Form (Appendix A)
33. Not applicable

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APPENDIX A

Culture, Social Networks and Well-Being

Study Leaders:
Dr. Irene Vitoroulis, School of Psychology, University of Ottawa
Dr. Tracy Vaillancourt, Faculty of Education, School of Psychology, University of Ottawa

Why are we doing this study?
This study is about the social networks of university students from diverse cultural backgrounds. We are interested in understanding how cultural processes, such as acculturation and cultural identity, play a role in social relationships and well-being. We are also interested in learning about students' experiences with aggression and discrimination, and how they are doing during the COVID-19 pandemic.

The results of this study should help us understand how different sources of social support help with students' well-being and integration to social and academic settings.

Who is needed for this study?
We are looking for university students from all levels of study (e.g., Undergraduate, Masters, Doctorate) between the ages of 17 and 24 years old. We are looking for students who come from any immigrant, refugee, ethno-cultural, and racialized background, as well as mainstream Canadian backgrounds.

What will happen during this study?
Participation in this study includes an online survey that will take about 45-60 minutes to finish. The survey will ask questions about your social networks, such as the characteristics of people you interact with, your cultural identity, experiences with aggression and discrimination, and your well-being.

To thank you for your contribution to this research study, your student email will be entered in a draw for a chance to win 1 of 20 $50 Visa gift certificates. The draw is open to all research participants who enter their student email in the draw, regardless of whether they decide to withdraw from further participating in the research study. If you decide to withdraw from the study, there will be an option to select 'skip' on all the questions and you will be able to provide your email to be eligible to receive the compensation. There will be attention check questions throughout this survey. If you fail to properly answer these questions, you will no longer be eligible for the draw. Upon completion of the study, email addresses will be randomly selected and winners will be informed by email. If a winner cannot be reached within 14 days from the date of the draw, the prize will be awarded to another randomly selected participant. The prize must be accepted as awarded and cannot be redeemed for cash. The student email provided when you enter the draw is collected for the purposes of contacting you if your email is selected in the draw. The contact information you have provided will be kept confidential and destroyed once the prizes have been awarded. Your email will be separated from your survey responses to ensure confidentiality and anonymity. We reserve the right to cancel the draw or cancel the awarding of the prize if the integrity of the draw or the research or the confidentiality of participants is compromised. The draw is governed by the applicable laws of Canada.

Data Quality
We ask that you do the survey all at once, without taking a break or leaving the survey open while you do something else. We will screen all surveys for invalid data. If fraudulent survey responses are identified, the research team will deem the survey responses as inadequate and withhold compensation and exclude the data. You should know that quitting the survey part way through or skipping items is always your choice but does affect the quality of our research.

Who will know what I said in this survey?
We will keep your answers anonymous and confidential. The only individuals who will get access to your information are the principal investigator and student researchers who are directly involved in this study. Given that the data are collected anonymously without any identifying information and that email addresses for the draw will not be linked to survey responses, the data cannot be withdrawn once they have been submitted.

Your responses to the survey questions will be combined with those of other participants and will be stored securely in a central database at uOttawa. Your personal information will not appear anywhere on the survey. We will protect your privacy by using a numerical code on your questionnaire.

This survey will be on Qualtrics. Data collected and stored in Qualtrics are managed by Qualtrics data security policies. Your data are encrypted and anonymized within this system. We will download the data from Qualtrics once the study is done and we will remove all data from the Qualtrics system. We will store the original data from this survey on an encrypted, external hard drive owned and stored securely by the study leaders.

The findings will help us learn about the social networks and well-being of university students from diverse cultural backgrounds to help improve students' social integration and well-being in schools and communities. The findings will be used for scientific publications, in which nobody will ever be identified – we are only interested in how people in general answered the questions in this survey.

Will anything bad happen during the study?
No risks are anticipated for participating in this type of research. Although completing the questionnaire may not always involve positive thoughts and feelings, it is our experience that participants do not suffer any negative consequences for participating. If you feel uncomfortable answering any of the questions, you can either skip the question or stop entirely. A link to a list of mental health resources will be displayed at the bottom of every page – if you felt upset about answering any of the questions, we encourage you to use these resources. Once you complete the survey, the list of resources will be automatically displayed. In order to minimize the risk of security breaches and to help ensure your confidentiality, we recommend that you use standard safety measures such as signing out of your account, closing your browser and locking your screen or device when you have completed the study.

Should you have any questions or concerns, please contact:
cdyd.lab@uottawa.ca

We would like to assure you that this study has received ethics approval from the University of Ottawa Research Ethics and Integrity Board (uOttawa REB #: H-06-21-7101). However, the final decision to participate is yours. If you have any comments or concerns resulting from your participation in this study, please contact the Protocol Officer for Ethics in Research, University of Ottawa, Tabaret Hall, 550 Cumberland Street, Room 154, Ottawa, ON K1N 6N5. Tel.: (613) 562-5387 Email: ethics@uottawa.ca

We invite you to print a copy of this form for your personal records. Please print or save this page for your records.

This research is funded by the Seed Funding Opportunity (SFO) awarded by the Faculty of Social Sciences.

Culture, réseaux sociaux et bien-être

Veuillez noter que ce sondage est uniquement offert en anglais

Responsables de l'étude:
Irene Vitoroulis, PhD, École de Psychologie, Université d'Ottawa
Tracy Vaillancourt, PhD, Faculté d'Éducation, École de Psychologie, Université d'Ottawa

Pourquoi faisons-nous cette étude?
Cette étude porte sur les réseaux sociaux d'étudiant-e-s universitaires de milieux culturels diversifiés. Nous sommes intéressés de savoir comment les processus culturels, tels que l'acculturation et l'identité culturelle, jouent un rôle dans les relations sociales et le bien-être. Nous sommes également intéressés de connaître les expériences des étudiant-e-s avec l'agression et la discrimination, et comment ceux-ci se portent durant la pandémie de la COVID-19.

Les résultats de cette étude devraient nous aider à comprendre comment différentes sources de soutien social aident au bien-être des étudiant-e-s et à leur intégration dans des contextes sociaux et académiques.

Qui cherchons-nous pour cette étude?
Nous cherchons des étudiant-e-s universitaires de tous les niveaux d'étude (p. ex., 1er cycle, maîtrise, doctorat) âgés de 17 à 24 ans. Nous cherchons des étudiant-e-s d'origines immigrées, réfugiées, ethnoculturelles et racisées, de même que des étudiants d'origine canadienne.

Qu'est-ce qui va se passer durant cette étude?
La participation à cette étude comprend un sondage en ligne qui prendra 45-60 minutes à compléter. Le sondage posera des questions concernant vos réseaux sociaux, tels que les caractéristiques des personnes avec qui vous interagissez, votre identité culturelle, vos expériences avec l'agression et la discrimination, et votre bien-être.

Pour vous remercier de votre participation à cette étude, votre adresse courriel étudiante sera incluse dans un tirage pour une chance de gagner 1 de 20 cartes cadeaux Visa de 50$. Le tirage est ouvert à tous les participants qui mettent leur adresse courriel étudiante dans le tirage, même s'ils décident de cesser la continuation de leur participation à l'étude. Si vous décidez de vous retirer de l'étude, chaque question a une option 'Skip' et vous pourrez donner votre courriel à la fin du sondage afin d'être admissible au prix. Il y aura des questions de contrôle d'attention dans le sondage. Si vous ne répondez pas de façon appropriée à ces questions, vous ne serez plus admissibles pour le tirage. Après l'achèvement de l'étude, les adresses courriel seront sélectionnées au hasard et les gagnants seront contactés par courriel. Si un gagnant ne peut pas être contacté dans les 14 jours suivants, le prix sera attribué à un autre participant choisi au hasard. Le prix doit être accepté tel quel et ne peut pas être échangé contre un équivalent financier. L'adresse courriel étudiante que vous fournissez pour le tirage sera uniquement utilisée pour vous contacter si votre courriel est sélectionné dans le tirage. Les renseignements dont vous nous faites part seront maintenus confidentiels et détruits une fois que le prix aura été attribué. Votre courriel sera séparé de vos réponses au sondage afin d'assurer la confidentialité et l'anonymat de vos réponses. Nous réservons de droit d'annuler le tirage ou l'attribution des prix si l'intégrité du tirage, de la recherche, ou de la confidentialité des participants est compromise. Ce tirage est effectué dans le respect des lois applicables du Canada.

Qualité des données
Nous demandons que vous complétiez de sondage d'un coup, sans prendre de pause ou laisser le sondage ouvert pendant que vous faites autre chose. Nous allons vérifier tous les sondages pour des données invalides. Si des réponses frauduleuses sont trouvées, l'équipe de recherche jugera les réponses au sondage inadéquates et retiendra le prix et exclura les données. Vous devez savoir qu'arrêter le sondage avant la fin ou sauter des questions est toujours votre choix, mais cela affecte la qualité de notre recherche.

Qui va connaître mes réponses au sondage?
Nous garderons vos réponses anonymes et confidentielles. Les seules personnes qui auront accès à vos données sont les chercheurs principaux et les chercheurs étudiant-e-s qui sont directement impliqués dans le projet. Puisque les données sont collectées de façon anonyme, sans aucune information personnelle, et que les adresses courriel ne sont pas liées aux réponses du sondage, les données ne pourront pas être retirées après la soumission du sondage. Vos réponses au sondage seront combinées avec celles des autres participants et seront entreposées en toute sécurité dans une base de données centrale à l'Université d'Ottawa. Vos informations personnelles n'apparaitront nulle part dans le sondage. Nous allons protéger votre vie privée en utilisant un code numérique sur votre questionnaire.

Ce sondage se fera sur la plateforme Qualtrics. Les données récoltées et entreposées dans Qualtrics sont gérées par les politiques de sécurité des données de Qualtrics. Vos données sont codées et rendues anonymes dans leur système. Une fois l'étude complétée, nous allons télécharger les données de Qualtrics et enlever toutes les données du système Qualtrics. Nous allons entreposer les données originelles de ce sondage dans un disque dur externe codé, détenu et stocké en toute sécurité par les responsables de l'étude.

Les trouvailles de cette étude nous aideront à mieux comprendre les réseaux sociaux et le bien-être des étudiants universitaires de différentes origines culturelles afin d'aider à améliorer les façons que les étudiants interagissent dans les écoles et les communautés. Les trouvailles seront utilisées pour des publications scientifiques, dans lesquelles personne ne sera identifié – nous sommes seulement intéressés de voir comment les personnes en général répondent aux questions de ce sondage.

Est-ce que quelque chose de mauvais arrivera pendant cette étude?
Il n'y a aucun risque anticipé avec la participation dans ce type de recherche. Bien que compléter le sondage risque de ne pas toujours résulter en des émotions et des pensées positives, c'est notre expérience qu'il n'y a pas de conséquences négatives associées à la participation à ce sondage. Si vous ne vous sentez pas à l'aise de répondre à certaines questions, vous pouvez sauter la question ou arrêter complètement. Une liste de ressources de santé mentale sera affichée au bas de chaque page – si vous vous sentez contrarié de répondre à n'importe laquelle des questions, nous vous encourageons à utiliser ces ressources. Une fois que vous terminerez le sondage, la liste des ressources sera automatiquement affichée.

Afin de minimiser les risques de bris de sécurité et pour assurer la confidentialité, nous recommandons d'utiliser des mesures de sécurité standards, telles que mettre fin à la session, se déconnecter de son compte, fermer son navigateur Internet et verrouiller son écran ou appareil après avoir terminé l'étude.

Si vous avez des questions ou des inquiétudes, veuillez contacter :
cdyd.lab@uottawa.ca

Nous voulons vous assurer que cette étude a reçu l'approbation du bureau d'éthique et d'intégrité de la recherche de l'Université d'Ottawa (# CÉR de l'Université d'Ottawa : H-06-21-7101). Néanmoins, la décision finale de participer est la vôtre. Si vous avez des commentaires ou inquiétudes à la suite de votre participation à cette étude, veuillez contacter le bureau d'éthique et d'intégrité de la recherche de l'Université d'Ottawa au (613) 562-5387 ou ethique@uottawa.ca.

Nous vous invitons à imprimer une copie de ce formulaire pour vos dossiers personnels.

Cette recherche est subventionnée par le programme de financement de démarrage (PFD) décerné par la Faculté des Sciences Sociales de l'Université d'Ottawa.

Using Point-of-View Wearable Technology as a Tool in Virtual Teaching Sessions to Supplement Clinical Skills Training: A Medical Student Perspective

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Date Submitted: August 6, 2022
Date Accepted: December 5, 2022
Date Published: July 19, 2024

DOI: https://doi.org/ 10.18192/uojm.v14i1.6483

Keywords: *medical students, medical education, clinical skills, COVID-19, virtual learning, point-of-view, wearable technology*

ABSTRACT

Introduction: The COVID-19 pandemic has forced many undergraduate medical programs to shift their preclinical curricula online, which has reduced student access to clinical skills sessions and caused gaps in students' knowledge.

Objective: This study sought to better understand the impact and role of virtual clinical skills training session using point-of-view (POV) live-streaming wearable technology to supplement medical students' learning.

Methods: 38 University of Ottawa medical students were recruited to participate in a 1.5-hour virtual clinical teaching session. An abdominal physical examination was broadcasted through two views (chest-mounted smartphone and room overview). Participants completed pre- and post-event questionnaires on their overall impression, satisfaction/challenges, and platform efficacy compared to other learning modalities.

Results: Differences were noted in participant engagement ($p=0.042$, Cohen's $d=0.48$), comparability to in-person encounters ($p<0.001$, Cohen's $d=0.75$), and confidence performing a physical exam ($p<0.001$, Cohen's $d=1.35$). Participants found the event was relevant to curriculum objectives (mean 4.55±0.69), engaging and interactive (mean 4.50±0.65), and reported good visualization through the broadcasted views (mean 4.61±0.59). All participants stated they were interested in attending similar sessions in the future.

Conclusion: This virtual clinical skill teaching session using POV technology was enjoyable and helpful in combating current COVID-related gaps in medical education. These results support the beneficial role of innovative virtual learning opportunities within medical school curricula. Future research should aim to evaluate the use of POV wearable technology in settings beyond the classroom.

RÉSUMÉ

Introduction: La pandémie de COVID-19 a contraint de nombreux programmes médicaux de premier cycle à transférer leur cursus préclinique en ligne, ce qui a réduit l'accès des étudiants aux sessions de compétences cliniques et a entraîné des lacunes dans les connaissances des étudiants.

Objectif: Cette étude visait à mieux comprendre l'impact et le rôle des sessions virtuelles de formation aux compétences cliniques utilisant la technologie vestimentaire de diffusion en direct du point de vue (PDV) pour compléter l'apprentissage des étudiants en médecine.

Méthodes: 38 étudiants en médecine de l'Université d'Ottawa ont été recrutés pour participer à une session d'enseignement clinique virtuel d'une heure et demie. Un examen physique abdominal a été diffusé à travers deux vues (smartphone monté sur la poitrine et vue d'ensemble de la pièce). Les participants ont rempli des questionnaires avant et après l'événement sur leur impression générale, leur satisfaction/problèmes et l'efficacité de la plateforme par rapport à d'autres modalités d'apprentissage.

Résultats: Des différences ont été observées au niveau de l'engagement des participants (p=0,042, d=0,48 de Cohen), de la comparabilité avec les rencontres en personne (p <0,001, d=0,75 de Cohen) et de la confiance dans la réalisation d'un examen physique (p <0,001, d=1,35 de Cohen). Les participants ont trouvé que l'événement était pertinent par rapport aux objectifs du programme (moyenne 4.55±0.69), engageant et interactif (moyenne 4.50±0.65), et ont rapporté une bonne visualisation à travers les vues diffusées (moyenne 4.61±0.59). Tous les participants ont déclaré qu'ils souhaitaient assister à des sessions similaires à l'avenir.

Conclusion: Cette session virtuelle d'enseignement des compétences cliniques utilisant la technologie PDV a été agréable et utile pour combattre les lacunes actuelles liées à la COVID dans l'enseignement médical. Ces résultats confirment le rôle bénéfique des possibilités d'apprentissage virtuel innovantes dans les programmes des écoles de médecine. Les recherches futures devraient viser à évaluer l'utilisation de la technologie portable PDV dans des contextes autres que la salle de classe.

INTRODUCTION

The COVID-19 pandemic has proven to be an obstacle to the provision of education to all students, particularly medical students across Canada who rely heavily on in-person sessions and clinical encounters. Many undergraduate medical programs responded to the pandemic by shifting components of their curriculum online due to safety mandates such as physical distancing.[1] In-person lectures, clinical programs, and patient encounters were replaced with online content such as pre-recorded videos and e-modules, or in some instances, suspended completely.[2] Challenges with virtual education have led to gaps in the current medical school curriculum.[3] Recent literature has discussed the rapid redevelopment of the medical curriculum in response to the COVID-19 pandemic, and calls have been made to develop innovations to deliver supplemental learning opportunities for medical students to address COVID-19-related gaps.[4-6] Before the pandemic, point-of-view (POV) learning and wearable technology proved to be an up-and-coming resource in healthcare and educational settings.[7] Lynch et al. described how POV video vignettes could be used to teach clinical skills to student paramedics, and Thomson et al. described how POV filming was effectively performed to successfully immerse fourth-year medical students in a ward simulation exercise.[8,9] Moreover, Teitelbaum et al. found that medical students preferred POV technology when compared to the third person view of pre-recorded videos followed by preceptor-led discussions.[10] As such, using POV-wearable technology provides promising potential as a tool for the training of medical students in our current virtual environment.

Previous literature has found that combining wearable live streaming devices with live video conferencing can replicate interactive learning environments that are comparable to in-person exposures.[3,7] Wintraub et al. evaluated several modalities of wearable technology and found the best device-accessory pairing for broadcasting virtual physical exams to be a chest-mounted smartphone using Zoom technology.[3,4] While wearable technologies appear useful in providing rich learning experiences in this study, it is important to build upon these findings and evaluate for generalizability and reproducibility at other educational institutions across Canada. The effectiveness, feasibility, and overall impact of POV filming on clinical skills development in medical students is an under-researched area.[4] As such, a clear need exists to expand upon the role of POV-wearable technology in medical education and to evaluate the perspectives of medical students on such technologies.

The remodeling of the undergraduate medical curriculum in the face of the COVID-19 pandemic continues to be a topic of interest among medical professionals and educators.[12,13] Our study aims to further investigate the effectiveness and feasibility of using POV-wearable technology as an adjunct to the University of Ottawa's clinical skills curriculum

(Physician's Skills Development (PSD) program) in order to simulate in-person learning experiences. Specifically, aiming to improve student engagement, bedside manner, and clinical competency. The goals of our study were to: (1) provide students with remote educational sessions to help mitigate the COVID-19-related gaps in the medical curricula and ensure students are achieving their core competencies; (2) engage participants as active agents in their learning by exploring their experiences and perspectives towards the use of POV technology in virtual education sessions; and (3) add to the growing literature of using wearable technology in medical education. Our research acts as a guide for those in charge of developing medical curricula or medical education researchers looking to improve upon the provision of virtual teaching sessions at their respective universities.

METHODS

Participants and Recruitment

This mixed methods study included two virtual clinical teaching sessions using POV wearable technology. Participants were University of Ottawa undergraduate medical students in their first, second, or third year. Students were recruited through local student-run associations (i.e., Family Medicine Interest Group, Aesculapian Society) via email and secure member groups. Interested participants self-enrolled by clicking on the link in the email and completing a form to register for the event. Thirty students were chosen to attend the event on a first-come first-serve basis and successful students were contacted via email. All other interested students were added to a waitlist in the case of a participant withdrawing. All participants, the tutor, and the standardized patient were provided with detailed information on the nature of the study, potential risks and benefits, and that they were free to withdraw from the study at any time. Participants were reassured that all efforts would be made to safeguard their personal information and ensure confidentiality be maintained. Consenting participants were provided preparation resources including information about the clinic skill being taught (i.e., abdominal physical examination) prior to the session. Participants were given the option to review the material beforehand to encourage active participation and discussion during the event. Ethics approval was obtained by the University of Ottawa's Research Ethics Board (REB #: H-09-21-7281).

Data Collection

As there were no suitable standardized and validated questionnaires available in the literature, two research assistance worked together to establish questionnaires using themes from current research as well as previous questionnaires used in relevant literature.[3,4,24] The questionnaires were reviewed for clarity and context by the two senior medical students, as well as one local family medicine resident, and two local family physicians with medical education experience. All questions were scored on a 5-point Likert scale with anchors ("Strongly Agree" to "Strongly Disagree"). Participants were asked to complete a brief pre-session survey one week before the event that described their concerns, comfort with, and expectations of the upcoming event. All participants took part in a 1.5-hour virtual teaching session that occurred via Zoom. The security of Zoom is acceptable for virtual clinical use by many hospitals associated with The University of Ottawa; nevertheless, participants were made aware of the minimal security risk inherent in its use before each event. During each session the tutor, a second-year family medicine resident from The University of Ottawa, used an iPhone 11 attached to a wearable chest strap to demonstrate an abdominal examination on a standardized adult patient. An additional camera was present during the examination to provide students with an alternate view of the exam and to optimize visualization. Participants provided verbal confirmation that all devices audio and visual were functioning properly. Physical distancing requirements and COVID-19 precautions were followed. Students were encouraged to interact with the tutor and ask questions using the microphone or Zoom chat message function. A research assistant facilitated the event and moderated the chat for questions in real-time. Immediately following the event, participants were emailed the post-event survey (Table 1) and given one week to complete it. Students were asked to elaborate on their overall impression of the technology, facilitators, and impact of the event. Events were recorded for future asynchronous learning opportunities and participants were made aware and provided written consent to this before commencing the session.

Data Analysis

All identifiable information was removed from the participant data, and it was stored on a secure, password-protected device. Two research assistants independently reviewed the data and means/standard deviations for each question were

calculated using Microsoft Excel. Participants' responses pre- versus post-event were compared via paired two-tailed t-tests to get a p-value and Cohen's d was completed to determine the relative effect size.[14] Researchers assessed effect size whereby values of 0.2–0.3 were considered small, 0.5 medium, and ≥ 0.8 large.[16] For this study, the p-value (<0.05) was evaluated in collaboration with the effect size to determine the overall significance of the intervention impact.[14] Research assistants collated participants' responses to the short answer questions into specific themes which were constantly assessed for accuracy and consistency throughout the research process.

RESULTS

Participant Demographics

Sixty medical students responded to recruitment and were sent the pre-event questionnaire to complete prior to the session. A total of 41 students (21 first event, 20 second event) attended the sessions and of these, 38 participants completed the post-event questionnaire. As such, the data from a total of 38 participants was evaluated (Figure 1). Medical student cohorts ranged from MD2025 (first-year students) to MD2023 (third-year students) with the majority of the 38 participants being in their first year of medical school (Table 2). Pre-event surveys were completed within one week before the event and post-event surveys were distributed immediately following the event and were completed within one week following the event.

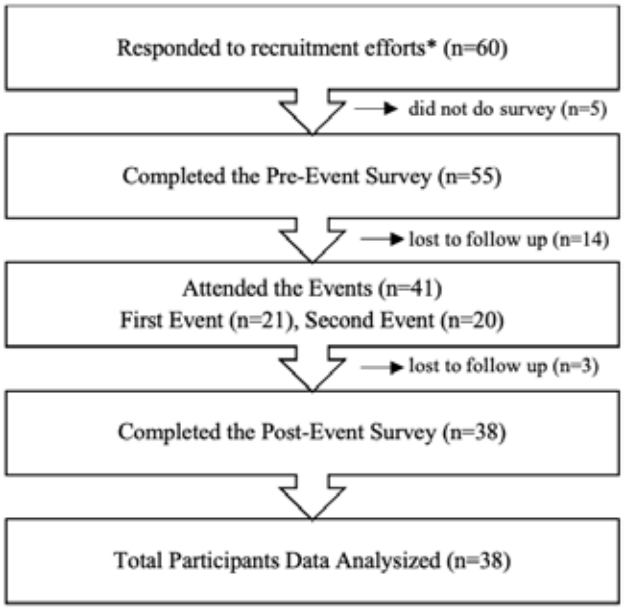

Figure 1. Participant Recruitment
Note: Participants were recruited on a first-come, first-serve basis with a maximum of 60 students

Participants' Perspectives of Virtual Learning Sessions

Participant responses pre- and post-event were compared using a 5-point Likert scale (Table 3). Participants reported significant changes with medium to large effect size in their confidence to perform a focused abdominal exam (2.63±1.15 pre-event to 3.95±0.77 post-event, p=<0.001, Cohen's d=1.35) and perceptions towards how the event compared to an in-person encounter (3.34±0.85 pre-event to 4.00±0.90 post-event, p=<0.001, Cohen's d=0.75). Of note, one participant reported that in some ways (i.e., visualization, interactions) the sessions were superior to in-person sessions. A significant difference with a nearly medium effect size was also reported in perspectives towards event engagement (4.58±0.68 pre-event to 4.87±0.53 post-event, p=0.042, Cohen's d=0.48). Overall, participants reported that the event was engaging and interactive (4.50±0.65), relevant to curriculum objectives (4.55±0.69), and that visualization was optimal (4.61±0.59). All participants agreed or strongly agreed that they were satisfied with the event and 31 participants (81.6%) agreed or strongly agreed similar events should be integrated into the pre-clerkship curriculum. Thirty-five participants (92.1%) agreed or strongly agreed that they were comfortable interacting with the tutor during the session and 36 participants (94.7%) agreed or strongly agreed that visualization of physical exam maneuvers was effective. Of note, all participants reported that they would be interested in attending a subsequent event focused on a different physical exam.

Session Strengths and Areas for Future Improvement

Participants were prompted to provide short answer responses on their experience of the event, what they found beneficial, and areas that could be improved. Participants' responses for both strengths and areas of improvement were collated into four major categories (i.e., video/audio, event organization, audience engagement, and curriculum integration; Table 4). Overall, participants enjoyed the session and found it beneficial for their learning. The most cited area for improvement pertained to audio quality. Despite this, participants supported the inclusion of similar sessions in their curriculum and preferred it over the physical examination videos that are currently used prior to PSD teaching sessions.

DISCUSSION

The COVID-19 pandemic has disrupted the traditional format of face-to-face training for medical students across Canada. In response, the rapid readjustment of the medical school curriculum has led to in-person activities (i.e., lectures, clinical duties, etc.) being suspended and replaced with virtual content in an attempt to fill these gaps.[2] Recent literature discussed the importance of using a "blended teaching" approach involving e-learning and traditional teaching methods to best improve medical student knowledge.[16] Wearable technology serves as an innovative adjunct and/or alternative to in-person teaching experiences in the current COVID-19 environment.[3,4,10] By using live video conferencing, our study aimed to investigate medical students' perspectives on the role of POV-wearable technology in simulating engaging, in-person learning experiences that successfully address medical education core competencies.

Participants' Perspectives of Virtual Learning Sessions

Given the current COVID-19 gaps in education, many educational institutions are working to improve their virtual teaching resources to provide quality education to students and to address core competencies.[18] Despite this, significant barriers to the adoption of e-learning by medical schools and concerns about the quality of education, particularly during preclinical medical training, exist.[19,20] Participants in this study reported that events were more engaging than pre-recorded videos, allowed for effective visualization of physical exam maneuvers, and improved confidence in performing an abdominal physical examination. Importantly, most participants found POV learning to be helpful and comparable to an in-person clinical skills session, and specifically 81.6% agreed that similar events should be integrated into the pre-clerkship curriculum. These perspectives align with findings from Wintraub et al. which suggest that chest-mounted smartphones are both an effective and efficient way of providing medical students with virtual POV physical exam demonstrations – particularly in the face of the COVID-19 pandemic.[3] Moreover, the findings echo those of Teitelbaum et al. who found that medical students viewed POV technology to be more engaging and ultimately improve knowledge retention when compared to pre-recorded videos followed by preceptor-led discussions.[10]

Prior to the event, participants reported feeling comfortable with the idea of learning in this nature, anticipated that they would enjoy the learning experience and that it would be beneficial for their learning. These high ratings are suspected to be related to students' limited exposure to physical examinations and a keen interest in learning. Findings from our study build on the evident pandemic-related gaps in medical education and showcase the strong desire of medical students to address these concerns. All participants were interested in attending subsequent sessions focused on a different physical examination and participants supported the integration of such events into the medical curriculum — reinforcing the interest and success of using POV wearable technology in clinical skills education.

The adoption of online learning will likely assume an important role in the teaching of medical students beyond the pandemic, including modalities such as mobile technology.[23,24] The additional application of online teaching methods within traditional medical education and career exploration can be anticipated nationwide as we continue to face the COVID-19 pandemic.[20,22] While these sessions cannot completely replace traditional face-to-face learning, our study supports blended learning methods (both virtual and in-person) which leads to better knowledge outcomes and translation compared to traditional learning.[10,25] Our study provides a framework for other Canadian medical schools to use and build upon. Considering the perspectives of participants in this study, this framework allows medical schools to capitalize on POV-wearable technology to address pandemic-related gaps in curriculum and provide high-quality, virtual learning opportunities for their students both amidst and beyond the current COVID-19 pandemic.

Session Strengths and Areas for Future Improvement

Participants reported feeling safe and comfortable interacting with the tutor and appreciated the use of a moderator to facilitate live questions. Similar to Teitelbaum et al. who found that two simultaneous views on a Zoom video call transformed the platform into a multi-perspective learning tool, our study suggests that a multi-camera perspective allows students to simultaneously visualize the physical exam and follow step-by-step explanations from the tutor.[10] Moreover, the virtual platform allowed tutors to effectively communicate with a greater number of students as compared to in-person small group learning sessions.

Event recordings provided students with the opportunity to review the session and engage in asynchronous self-learning. This closely aligns with existing literature which found that pre-recorded POV videos could enhance understanding prior to clinical application[17,25,26] and improve skills development within health education.[8,27] Several students expressed interest in substituting pre-recorded videos from the current medical curriculum with interactive sessions such as the one in this study.

Overall, students greatly valued the opportunity to learn with different modalities and these results highlight the role of live POV-wearable technology within the medical curriculum. Suggested areas of improvement include clearer audio quality, integrating knowledge after the session, and hosting sessions in concurrence with curriculum content. Participants' suggestions align with the understanding that the use of different mediums (i.e., classroom, virtual sessions) often leads to increased knowledge retention.[11]

Study Strengths and Limitations

Gathering feedback from students allowed this study to better appreciate medical students' perspectives and advocate for their involvement in discussions surrounding medical curricula. The reproduction of similar results across two events helps to strengthen the validity of our findings. The inclusion of a diverse student population (i.e., cohort, gender) contributed to the generalizability of the results. When interpreting the study, it is important to acknowledge its limitations. In this study, two major limitations included sample size and selection bias. The sample size (30 students per session) was selected to ensure participants felt comfortable interacting in a small group environment. During recruitment, several students were lost to follow-up, likely due to time conflicts, student over-commitment, or loss of interest. Despite this, our study had sufficient participants to achieve saturation regarding the usability and effectiveness of the teaching platform. Secondly, while the session was made available to all students within Ottawa's Faculty of Medicine, participants consisted mainly of first- and second-year students. This increased interest is likely related to the disproportionate impact COVID-19 has had on the clinical teaching of these cohorts. As such, these findings may not reflect the perspectives of all Canadian medical students. Moreover, participants volunteered for this study and were chosen based on a first-come, first-serve basis; possibly resulting in a selection bias for those students who were more keen or eager to learn. Lastly, participants' varying experiences in terms of their medical training (e.g., first-year, third-year) may have impacted their opinions towards the session's content, resulting in feedback that may not be based purely on the POV-wearable technology intervention.

CONCLUSIONS AND FUTURE RESEARCH

Overall, this study drew attention to the current COVID-19-related gaps that exist in medical curricula and demonstrated that POV-wearable technology is an accessible, innovative, and evidence-based tool to provide medical students with virtual clinical skills development sessions that address these gaps. Students appreciated additional clinical training experiences and viewed these live POV sessions as engaging alternatives to traditional physical examination sessions. By obtaining learner perspectives, our study integrated medical students as active agents in their learning and demonstrated their interest in participating in and receiving additional resources such as this to be implemented as a permanent tool. With the use of recordings, these sessions can be used as a longitudinal and asynchronous educational resource toward a blended learning approach for current and future medical students. The findings in this study serve as a strong foundation on which Canadian medical schools can build upon to incorporate virtual learning platforms into their medical curricula, to improve students' core competencies. Further research should look to build upon the findings by incorporating participant feedback (i.e., external microphone use, aligning events with curriculum) and increasing sample size and variability. Furthermore, future research should look to evaluate the use of POV-wearable technology in settings beyond the classroom (i.e., clinical observerships, procedural skills, rural medicine opportunities) given that virtual learning will likely persist as an adjunctive teaching platform in medical education beyond the current COVID-19 pandemic.

Conflicts of interest: None

Funding: Funding was obtained from The University of Ottawa Department of Family Medicine for the chest strap and compensation for the tutor.

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Table 1. Pre- and Post-Event Questionnaires

Pre-Event Questions	Post-Event Questions
Multiple-Choice 1. I am comfortable with the idea of learning clinical skills in this manner. 2. I will enjoy this learning experience. 3. This experience will be beneficial for my learning.EsP 4. Observing the patient interaction virtually will be comparable to observing an in-person clinical encounter. 5. This session will be more engaging than watching pre-recorded video vignettes for the same clinical skills. 6. I feel confident when it comes to performing a focused physical examination 7. I do not anticipate any problems with learning clinical skills from a virtual curriculum. 8. After this session, I will be confident in my ability to perform the clinical skills demonstrated. 9. Overall, I have high expectations for this learning session. 10. What do you hope to gain from this learning experience?	*Multiple-Choice* 1. After this session, I am comfortable with the idea of learning clinical skills in this manner. 2. I enjoyed this learning experience. 3. This experience was beneficial for my learning and improved my overall knowledge. 4. Observing the patient interaction virtually was comparable to observing an in-person clinical encounter. 5. This session was more engaging than watching pre-recorded video vignettes for the same clinical skills. 6. I feel more confident when it comes to performing a focused abdominal examination. 7. The content of the clinical skills session was relevant and clearly linked to course objectives. 8. I was engaged and felt comfortable interacting with the tutor during the session. 9. I was able to effectively visualize the physical exam maneuvers performed in this teaching session. 10. How would you rate your overall satisfaction with this teaching session? 11. How comparable is this learning experience to an in-person clinical encounter? 12. I think that virtual clinical teaching sessions, such as this, should be incorporated into the pre-clerkship curriculum? 13. Would you be interested in attending a subsequent session focused on a different physical examination?
Short Answer 1. What do you hope to gain from this learning experience? 2. What concerns, if any, do you have about learned this way?	*Short Answer* 1. Which elements of this clinical skills session did you like the most? 2. Which elements of this clinical skills session could be improved? 3. Please provide any additional comments, suggestions, or feedback for the research team/tutor or regarding the overall experience.

Note: For the multiple-choice questions, participants were required to select one answer that best described how they felt about the above statements. There were five answers, ranging from strongly disagree (1) – to strongly agree (5).

Table 2. Participant Demographics

	Participants	Lost to Follow Up	Total
n	38	17	55
Cohort	24 First Year 8 Second Year 6 Third Year	10 First Year 6 Second Year 1 Third Year	34 First Year 14 Second Year 7 Third Year
PG	8M, 30F	4M, 13F	12M, 43F

n=number of participants, PG=Perceived Gender, M=male, F=female

Table 3. Participant (n=38) responses to pre- and post-event questionnaires using a 5-point Likert scale

Questions	Strongly Disagree (%)	Disagree (%)	Neutral (%)	Agree (%)	Strongly Agree (%)	Mean score ± SD	p-value Cohen's D
Q. After this session, I am comfortable with the idea of learning clinical skills in this manner.							
Pre-event	0 (0%)	0 (0%)	12 (31.6%)	12 (31.6%)	14 (36.8%)	3.97 ± 0.88	0.11
Post-event	0 (0%)	1 (2.6%)	3 (7.9%)	18 (47.3%)	16 (42.1%)	4.29 ± 0.73	0.40
Q. I enjoyed this learning experience.							
Pre-event	0 (0%)	0 (0%)	4 (10.5%)	11 (28.9%)	23 (60.5%)	4.50 ± 0.69	0.18
Post-event	0 (0%)	0 (0%)	0 (0%)	13 (34.2%)	25 (65.8%)	4.66 ± 0.48	0.27
Q. This experience was beneficial for my learning and improved my overall knowledge.							
Pre-event	0 (0%)	0 (0%)	0 (0%)	14 (36.8%)	24 (63.2%)	4.63 ± 0.49	0.83
Post-event	0 (0%)	0 (0%)	1 (2.6%)	13 (34.2%)	24 (63.2%)	4.60 ± 0.30	0.07
Q. Observing the patient interaction virtually was comparable to observing an in-person clinical encounter.							
Pre-event	0 (0%)	5 (13.2%)	18 (47.4)	12 (31.6%)	3 (7.9%)	3.34 ± 0.85	<0.001*
Post-event	0 (0%)	3 (7.9%)	7 (18.4%)	16 (42.1%)	12 (31.6%)	4.00 ± 0.90	0.75
Q. This session was more engaging than watching pre-recorded video vignettes for the same clinical skills.							
Pre-event	0 (0%)	0 (0%)	3 (7.9%)	10 (26.3%)	25 (65.8%)	4.58 ± 0.68	0.042*
Post-event	0 (0%)	1 (2.6%)	0 (0%)	2 (5.3%)	35 (92.1%)	4.87 ± 0.53	0.48
Q. I feel more confident when it comes to performing a focused abdominal examination.							
Pre-event	5 (13.2%)	16 (42.1%)	6 (15.8%)	10 (26.3%)	1 (2.6%)	2.63 ± 1.15	<0.001*
Post-event	0 (0%)	0 (0%)	12 (31.6%)	16 (42.1%)	10 (26.3%)	3.95 ± 0.77	1.35
Q. The content of the clinical skills session was relevant and clearly linked to course objectives.							
Post-event	0 (0%)	1 (2.6%)	1 (2.6%)	12 (31.6%)	24 (63.2%)	4.55 ± 0.69	—
Q. I was engaged and felt comfortable interacting with the tutor during the session.							
Post-event	0 (0%)	0 (0%)	3 (7.9%)	13 (34.2%)	22 (57.9%)	4.50 ± 0.65	—
Q. I was able to effectively visualize the physical exam maneuvers performed in this teaching session.							
Post-event	0 (0%)	0 (0%)	2 (5.3%)	11 (28.9%)	25 (65.8%)	4.61 ± 0.59	—
Q. How would you rate your overall satisfaction with this teaching session?							
Post-event	0 (0%)	0 (0%)	0 (0%)	15 (39.5%)	23 (60.5%)	4.61± 0.50	—
Q. I think that virtual clinical teaching sessions, such as this, should be incorporated into the pre-clerkship curriculum?							
Post-event	0 (0%)	3 (7.9%)	4 (10.5%)	10 (26.3%)	21 (55.3%)	4.29 ± 0.96	—

p-value <0.05=significant, Cohen's d = 0.2–0.3 small, 0.5 medium, and ≥ 0.8 large effect size

Table 4. Participant perspectives on the strengths and areas of improvement of events

Session Strengths	Areas of Improvement
Video/Audio	**Video/Audio**
"I really enjoyed the chest-mounted camera point-of-view. Great visualization (and sound) during percussion and inspection." "Having the multi-camera perspective was extremely beneficial as some features of the physical exam can be hard to see at a distance and the camera resolution was sufficient." "The camera set up was great - it was helpful to have the POV angle & the overview angle to see the doctor's perspective." "All parties involved seemed to know how to navigate the technology and the multiple views helped with the audio." "I really liked the camera that allowed us to see everything being done, as opposed to the stationary one."	"When the clinician was percussing the abdomen, we couldn't always clearly hear the sounds. Perhaps this could be fixed by using a microphone instead of using the camera microphone." "Perhaps providing the patient with a microphone so their voice is clear when responding." "The audience couldn't hear the percussion very well, perhaps a better microphone could pick up the sound differences with percussion better (i.e., tympanic vs. dull)." "Consider adding in sound effects of certain components such as percussion so students can better appreciate the sounds."
Event Organization	**Event Organization**
"I was grateful for the host reading questions out loud for everyone. Having moderator was useful to facilitate." "I really enjoyed the setup and organization of the session. Specifically, having small group interactive sessions created a safe and effective learning environment." "The event was a good pace and approachable format." "Dr. Horner was systematic and explained the steps of the physical exam clearly. As a first-year student it was helpful."	"Adding a mock case at the end would be great. I.e., having a patient with lower right quadrant pain and going through the DDx and special tests together to see how the physician uses their exam to make decisions and apply what we learned." "Talking about what you might write in the SOAP note for this patient would be great practice for pre-clerkship students." "Perhaps attendees could partner up and do different aspects of the exam and the tutor could give us live feedback."
Audience Engagement	**Audience Engagement**
"The resident was experienced and kind. I liked how interactive it was and how engaging and thorough his explanations were" "I really enjoyed how the resident took the time to walk us through the exam. I appreciated how he paused to let us assimilate and ask questions at various points." "The resident was informative/engaging (spoke to the camera, quizzed and encouraged students, great learning environment)." "I enjoyed that the session was occurring in real-time and that it was interactive. This provided the opportunity to ask questions."	"Consider online answering software to promote engagement." "Consider demonstration with a real-life patient encounter." "I felt the demonstrator was sometimes speaking a bit too fast. Consider slowing down the pace for better understanding." "We were unable to practice and get feedback from the physician which we likely would in person." "Consider a hybrid approach, where videos would be pre-recorded at high production value, and someone was there to answer questions and clarify."
Curriculum Integration	**Curriculum Integration**
"These sessions could replace the PSD videos students are asked to watch before in-person clinical sessions." "It was more engaging and helpful than pre-recorded videos." "I found the session very interactive and refreshing compared to the pre-recorded videos we watch for current PSD sessions." "In some ways, the angles were even better than in person (esp. in bigger groups) as we could all see the exam and there was no awkward shuffling trying to see what the tutor's doing."	"Hold future sessions on topics that students learn in first year. I would enjoy seeing exams that go along with the curriculum." "Send out the abdominal booklet a few days earlier to allow students additional time to review prior to the event." "Having a session on something already learned in class would be beneficial to better compare the two learning environments. "Referring to the PSD guide more frequently during the session would have helped orient the learners to the skill being taught."
Overall Impression	
"I would gladly learn more clinical skills this way, it is much better than the current PSD online lectures where we watch videos or look at images of the tests being performed." "Was incredibly well run and greatly appreciated. It was clear the team put in a lot of effort." "Two camera views were very helpful and are often lacking from faculty-run virtual clinical skills sessions." "I really enjoyed this event and would definitely do it again if offered." "For me personally I found this session very interactive, and it almost replaces in-person learning" "I enjoyed this session and got a lot from it. Looking forward to attending more in the future."	

Non-Pharmacological Interventions for the Treatment of Raynaud's Phenomenon: A Systematic Review

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Date Submitted: January 15, 2022
Date Accepted: February 27, 2022
Date Published: July 19, 2024

DOI: https://doi.org/10.18192/uojm.v13i1.6175

Keywords: *Raynaud's phenomenon, non-pharmacologic interventions, rheumatology, dermatology*

ABSTRACT

Objective: The objective of this systematic review is to describe existing literature pertaining to the use of non-pharmacological interventions (NPIs) for the management of primary or secondary Raynaud's Phenomenon (RP) compared to placebo.

Methods: The Cochrane Central Register of Controlled Trials, MEDLINE, and EMBASE were searched from their inception to the present for randomized controlled trials and clinical trials for studies assessing the therapeutic effects of NPIs in primary or secondary RP. The studies were screened, and data were extracted by two reviewers. The major outcomes assessed included frequency (per week) and duration (minutes) of attacks and pain.

Results: We found 23 parallel or crossover RCTs, 5 of which were not discussed in this review. The categories of NPIs included acupuncture and other needling techniques (n=4), temperature biofeedback (n=4), lasers and electrotherapy (n=5), exercise therapy (n=2), gas therapy (n=1), therapeutic gloves (n=1), and ischemic preconditioning (n=1). Most studies demonstrated trends towards therapeutic benefit; however, there was substantial heterogeneity amongst the studies. Laser therapy had the most consistent evidence; 60% and 75% of the studies reported significant improvements in frequency of attacks per week and pain. Acupuncture therapies had minimal statistically significant benefits, and the data for temperature biofeedback were inconsistent and of low -quality. Exercise therapy is more recently being explored, showing a marked therapeutic benefit for pain.

Conclusion: The evidence is limited and inconsistent; however, the studies demonstrated trends towards therapeutic benefits, with laser and electrotherapy having the most consistent evidence. Further high-quality and multi-center RCTs are required.

RÉSUMÉ

Objectif: L'objectif de cette revue systématique est de décrire la littérature existante relative à l'utilisation d'interventions non pharmacologiques (INP) pour la gestion du phénomène de Raynaud (PR) primaire ou secondaire, en comparaison avec un placebo.

Méthodes: Le Registre central Cochrane des essais contrôlés, MEDLINE et EMBASE ont été consultés depuis leur création jusqu'à aujourd'hui pour des essais contrôlés randomisés et des essais cliniques pour des études évaluant les effets thérapeutiques des INP dans la PR primaire ou secondaire. Les études ont été sélectionnées et les données ont été extraites par deux examinateurs. Les principaux résultats évalués comprenaient la fréquence (par semaine) et la durée (en minutes) des crises et de la douleur.

Résultats: Nous avons trouvé 23 ECR parallèles ou croisés, dont cinq n'ont pas été examinés dans le cadre de la présente analyse. Les catégories d'INP comprenaient l'acupuncture et d'autres techniques d'aiguilletage (n=4), la rétroaction biologique sur la température (n=4), les lasers et l'électrothérapie (n=5), la thérapie par l'exercice (n=2), la thérapie par les gaz (n=1), les gants thérapeutiques (n=1) et le préconditionnement ischémique (n=1). La plupart des études ont montré des tendances vers un bénéfice thérapeutique; cependant, il y avait une hétérogénéité substantielle entre les études. La thérapie au laser est la plus cohérente; 60 % et 75 % des études ont fait état d'améliorations significatives de la fréquence des crises par semaine et de la douleur. Les thérapies par acupuncture n'ont apporté que des avantages minimes statistiquement significatifs, et les données relatives au biofeedback de température étaient incohérentes et de faible qualité. La thérapie par l'exercice a été explorée plus récemment et a montré des avantages thérapeutiques marqués pour la douleur.

Conclusion: Les preuves sont limitées et incohérentes; cependant, les études ont démontré des tendances vers des avantages thérapeutiques, le laser et l'électrothérapie ayant les preuves les plus cohérentes. D'autres ECR multicentriques de haute qualité sont nécessaires.

INTRODUCTION

Raynaud's phenomenon (RP) is characterized by the vasospasm of arteries or arterioles of the extremities leading to pallor, cyanosis, and/or redness and is associated with significant morbidity.[1,2] These morbidities include severe symptoms leading to tissue loss, digital ulcers, and amputations.[2] Primary RP is idiopathic, and it accounts for the majority of cases, with a median age of onset around 14 years of age. Secondary RP develops as a result of underlying disorders, including connective tissue diseases such as systemic sclerosis and systemic lupus erythematosus.[2] The latter type of RP has a later onset, with a median age of onset around 40 years. Common triggers of RP attacks include exposure to cold temperatures and emotional stress.[3] Primary RP is the most common type of RP, accounting for 80-90% of cases, compared to 10-20% of secondary RP. The prevalence of RP [primary and secondary] in the general population is around 3-5%,[4,5] being more common amongst women. Diagnosis of primary RP is based on patient history and ruling out the presence of underlying causes, whereas the diagnosis of secondary RP includes an older age of onset with more severe symptoms and laboratory tests that suggest an underlying connective tissue disease, in addition to microscopy of the nail folds indicating the presence of microvascular disease.[2]

The pathogenesis of RP has not been fully elucidated; it is hypothesized to be attributable to abnormalities in blood vessels, neural control of vascular tone, and intravascular mediators.[1] Vascular abnormalities are more severe in secondary RP.[1,2] This possibly explains the irreversible digital ischemia seen in RP secondary to systemic sclerosis spectrum disorders. Secondary RP is often associated with microvascular structural abnormalities, and RP has been postulated to be associated with hormonal factors.

These pathophysiologic differences are thought to explain, in part, the variability in responses to treatment amongst patients with RP. As such, reviewing the use of non-pharmacological interventions (NPI) would help summarize the alternative therapies that are available to manage RP. NPIs also have fewer adverse effects. Although several pharmacological interventions are well established as options for treatment of RP,[6-8] describing the role of NPIs is of interest to those interested in adjuvant therapies. There are no specific clinical guidelines pertaining to the use of NPIs for RP.[9]

NPIs are used to modify lifestyles and educate patients in recognizing reflex vasospasm and identify factors leading to attacks such as sudden temperature changes, digital trauma, smoking and drugs.[1,10] NPIs include behavioural therapies, skin temperature biofeedback, lifestyle changes such as managing stress and smoking cessation, and acupuncture/acupressure.[3,11-13] In our review, NPIs are defined as therapeutic modalities that exclude oral, subcutaneous, or intramuscular pharmaceuticals or oral supplements (e.g., vitamins, minerals, herbal extracts, diets etc.).

The primary objective of this systematic review is to describe existing literature pertaining to the use of NPIs for the management of RP in comparison to placebo. We hypothesize that NPIs are beneficial treatments for RP. The study will allow us to better understand the use of NPIs as potential adjuvants of pharmacological treatments and provide a basis for identifying those NPIs with the most promising potential to explore the synergies.

METHODS

This systematic review was conducted in accordance with the *Cochrane Handbook for Systematic Reviews of Intervention* guidelines.[14] Further details can be found in our study protocol, accessible through the University of Ottawa Journal of Medicine.

Eligibility Criteria

We included randomized controlled trials (RCTs) and controlled clinical trials (CCTs), including cross-over and parallel designs pertaining to any NPI's as compared to placebo for RP. There was no language restriction. The study subjects must have been >18 years of age with a diagnosis of primary or secondary RP.

Outcomes

We measured the following major outcomes:

1. Frequency of attacks (average number per week or change in frequency per week)
2. Duration of attacks (average duration in minutes)
3. Pain
4. Withdrawals (any withdrawals from studies due to adverse effects)
5. Serious adverse events (adverse effects leading to withdrawal from study and hospitalization or death)

The minor outcomes included:

6. Patient global assessment
7. Physician's global assessment (physician assessed measure of disability due to RP)
8. Healthcare assessment questionnaires

Electronic Searches

The search was conducted using the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, and EMBASE from their inception to the present. We screened the references of all primary and review articles for additional references. The search terms included: "*Raynaud Disease, Vasospasm, raynaud*" plus validated study design filters for RCTs for Medline and EMBASE. Details of the search strategies are available in Supplementary 1, which is a component of our study protocol.

Data Collection and Extraction

We dual-screened all abstracts and titles and full-text articles amongst the reviewers. One reviewer (F.M.) screened all abstracts, and four other reviewers (H.C., S.S., S.P., M.A.) screened the studies equally amongst themselves. We independently extracted data twice amongst the reviewers then combined. We resolved all disagreements and discrepancies in data collection through discussion amongst the reviewers and consulting a third reviewer (N.M. and P.T.).

For studies presenting the frequency of attacks per day, we multiplied the outcome by 7 to standardize the data to the frequency of attacks per week. We made other necessary adjustments to standardize the units for each outcome, and the standard deviation (SD) was imputed accordingly when necessary. For studies presenting the change in outcome from a baseline value, we subtracted the change from the baseline to compute the outcome post-treatment. For these data, we used the SDs from other similar studies and methodologies; a new SD was not computed. For studies presenting data only on figures/graphs without providing exact measurements, we extrapolated the data from these figures/graphs.

We have presented the data in forest plots (without a final total) to provide an overview of the size and direction of effects and the general trends. We used The Nordic Cochrane Centre, The Cochrane Collaboration Review Manager (RevMan),[15] version 5.4 software for the analyses.

Assessment of Risk of Bias in Included Studies

Two review authors independently assessed the risk of bias for each included study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions*,[14] and we resolved the conflicts upon discussion. We used the following domains to make a judgement on the overall risk of bias: 1) random sequence generation: checking for possible selection bias, 2) allocation concealment: checking for possible selection bias, 3) blinding of participants and personnel: checking

for possible performance bias, 4) blinding of outcome assessment: checking for possible detection bias, 5) incomplete outcome data: checking for possible bias due to attrition and methods used to handle missing outcome data, 5) selective outcome reporting: checking for possible reporting bias, 6) other bias: checking for bias not covered through 1 to 5 above.

Metanalysis

Due to the heterogeneity of the populations, time ascertainment and methodologies of the articles, in addition to the limited amounts of high-quality articles, metanalysis could not be conducted (Supplementary 2 describes our plan for meta-analysis in our protocol).

RESULTS

We performed the search on June 8th, 2021, which yielded 6892 studies; there were 1617 duplicates (Figure 1). Out of 5275 articles, 86 articles underwent full-text review twice, out of which 23 articles were identified to be included in this review (12 articles either had an incorrect study design (i.e., not an RCT or CCT, or they were ongoing trials)).

Furthermore, 5 articles are not reviewed for the following reasons: The study by Junger et al.[16] could not be translated to English in a timely manner thus, it is not included in this review. We are waiting for an assessment for the other 4 studies, as we have emailed the authors for clarifications regarding their study design and data. The study by Guo et

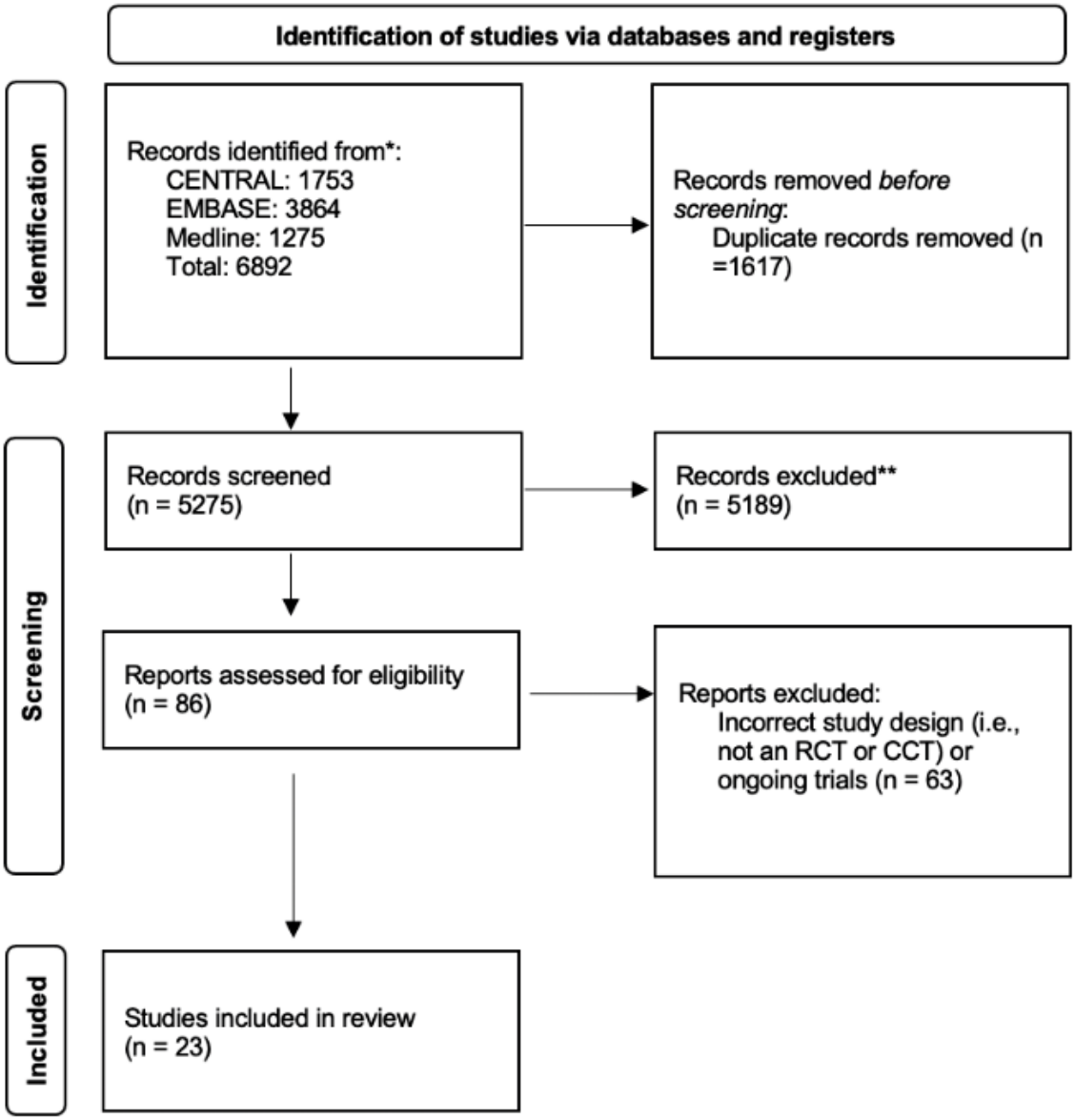


Figure 1. Flowchart of the Identification, Screening, and Inclusion of Studies

al.[17] was excluded as it is was unclear whether the authors differentiated patients with RP from patients with systemic scleroderma when reporting the outcomes. Freedman et al.[12] compared temperature biofeedback with electromyography. However, the pre-treatment frequency of attacks were markedly different (115.4 vs 13.1, respectively), and there was no clear description of the patient demographics in each group. Although Dabek et al.[18] discuss changes in pain and frequency of attacks after relaxation therapy, they do not provide the initial baseline values for these outcomes. Zhou et al.[19] was not discussed as it is unclear whether the data presented differentiated patients with RP from patients with diffuse systemic sclerosis.

The study characteristics and participant demographics are summarized in Tables 1 and 2. Out of the 18 studies discussed in this review, 3 are crossover RCT 20-22 and 15 are parallel RCTs. Four studies describe the use of acupuncture, acupressure, or warm needling as therapies, 4 studies use skin biofeedback temperature, 5 studies use lasers or electrotherapy, 2 studies assess the use of exercise/physical therapy as a NPI for RP, 1 study describes natural gas therapy, 1 study describes the use of thermal gloves, and 1 study assesses the role of ischemic preconditioning in treating RP. All but 2 studies include placebo or control interventions; Appiah et al.[11] and Sporbeck et al.[23] compared an acupuncture intervention group with a no treatment group.

The sample sizes range from 18 to 155 participants. The study by Raynaud's Treatment Study Investigators[24] had the largest sample size, including 81 participants in the intervention group and 74 participants in the control group. The age of the participants ranged from 24 to 69.6 years, and most of the studies had a predominance of female participants. The disease duration of RP ranged from 1.5 to 24 years. Seven of the 18 studies merely include participants with primary RP, whereas 5 studies include both primary and secondary RP (Table 2).

RISK OF BIAS

The risk of bias was assessed based on a variety of parameters regarding allocation, blinding, reporting. Each was judged based on high risk, low risk, or unclear. Most studies are detailed in their reporting and have low risks of bias. For example, 94% (17/18) of studies are at low risk for selective outcome reporting. In contrast, over half of the studies have an unclear risk or high risk of bias when evaluated regarding the blinding of participants. Due to the nature of the interventions, it is not always possible to keep them concealed. A 2018 study by Mitropoulos et al.[25] compared different types of exercises. In this situation, the participants cannot be blinded as they must perform actions based on assigned movements that will be known. In contrast, however, the study by Schmidt et al.[26] had a low risk of bias in most criteria as it kept the allocation concealed and the participants and outcome assessors blinded. The only personnel who knew which treatment group a patient was in, were those administering the intervention. The way this study was conducted eliminates most possibilities of bias. Al-Awami et al.[27] similarly conducted a high-quality study comparing low-level laser therapy to placebo therapy.

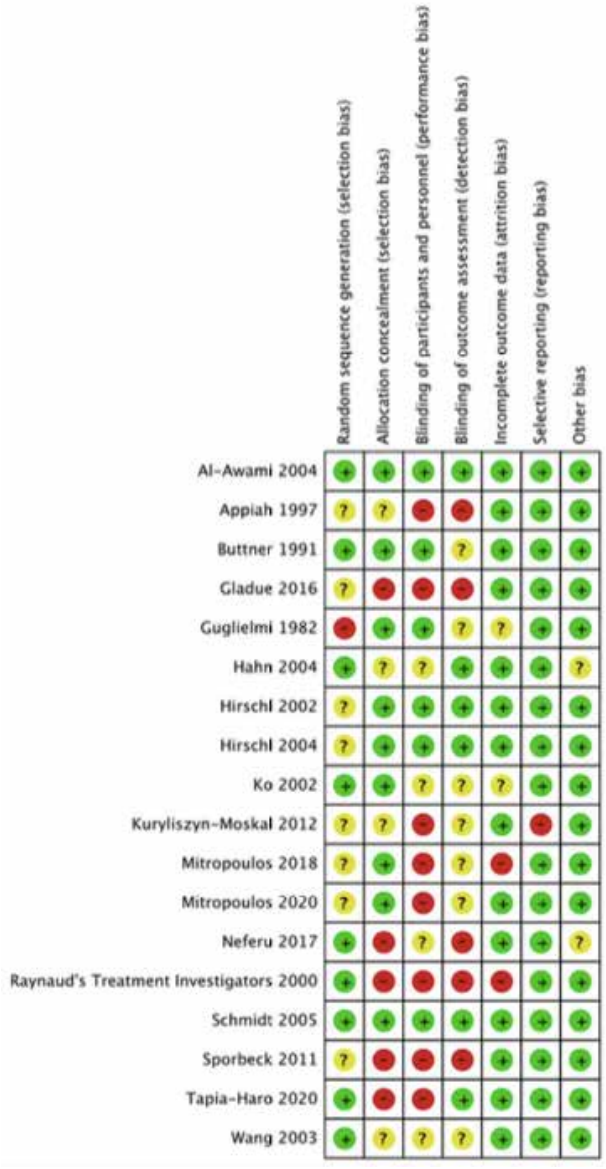


Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

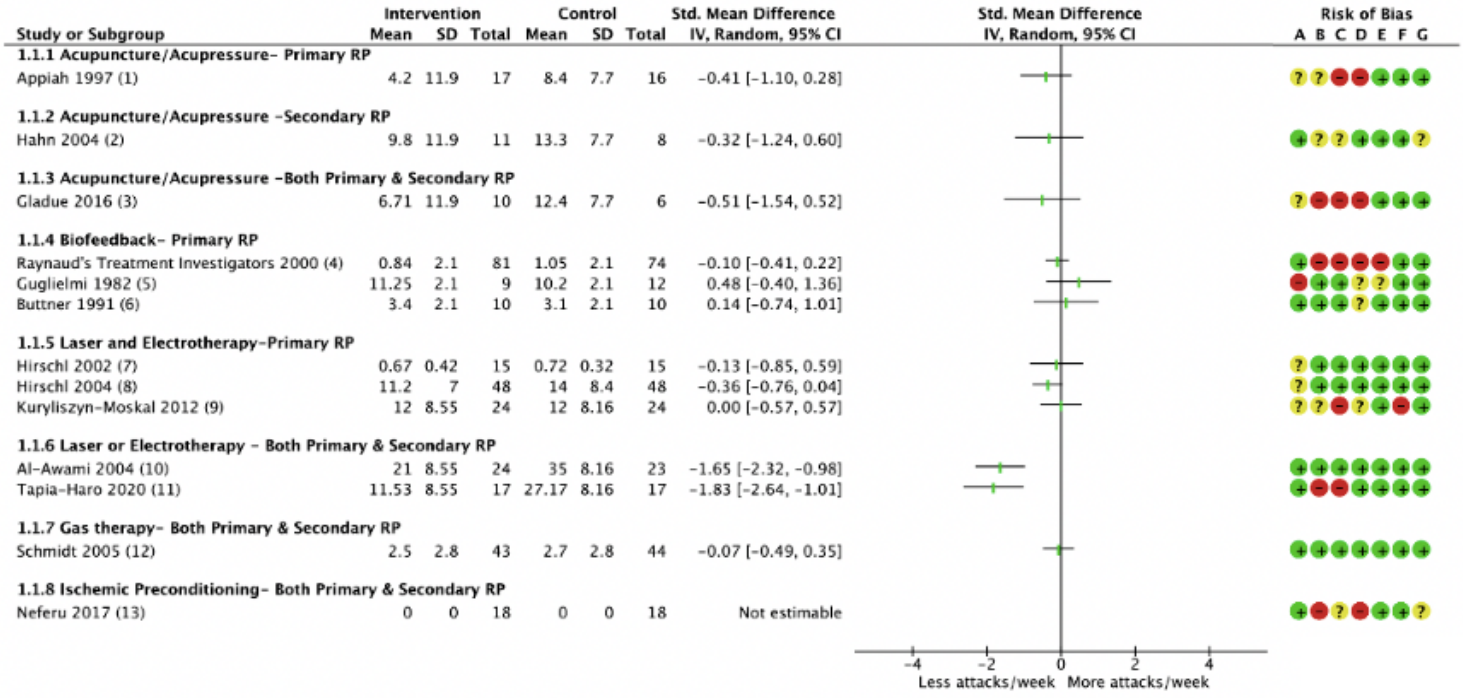
They clearly stated their blinding and randomization process, and clearly indicated that the patients and evaluators were not aware of the study protocol. In addition, the baseline characteristics of participants in the intervention and placebo groups were quite similar.

REVIEW AND ANALYSIS OF THE EFFICACY OF NON-PHARMACOLOGIC INTERVENTIONS

The forest plots (Figures 3, 4, and 5) summarize the data on major outcomes, including mean frequency of attacks per week, the average duration of attacks (minutes), and pain (scale 0 to 10) for the NPIs in treating primary or secondary RP. As a meta-analysis could not be completed, a total is not provided in the plots.

Acupuncture and Other Needling Therapies

Hahn et al.[28] compared 8 weeks of weekly acupuncture at 10 points with a sham acupuncture control in patients with secondary RP. They presented their frequency of attacks per day averaged over a 12-week period; when standardized, the acupuncture group had 9.8 (11.9) versus 13.3 (7.7) attacks per week in the placebo group. This difference was not statistically significant. Similarly, Appiah et al.[11] compared 7 sessions of acupuncture with moxibustion heat therapy with a no-treatment group in primary RP and found that the acupuncture group had fewer attacks per week (4.2 [11.9] vs 8.2 [7.7]) at 12 weeks. The overall reduction of attacks between the two groups was statistically significant (p=0.03). This was standardized from attacks



Footnotes
(1) Week 12. Means multiplied by 7. SD imputed from Hahn 2004.
(2) Week 12. Means multiplied by 7.
(3) Week 8. Change in mean subtracted from baseline; SD imputed from Hahn 2004.
(4) 2 month. Means multiplied by 7. SD imputed from Buttner 1991.
(5) Week 4. The data was provided in total period over 5 months, the means were divided by 20 weeks. SD imputed from Buttner 1991.
(6) Week 5.
(7) Week 3. RCT crossover.
(8) Week 3. Means multiplied by 7. RCT Crossover.
(9) Week 3. Data extracted from a graph, specific means were not provided. SD imputed from Tapia-Haro 2000, as this was most similar study.
(10) Week 6. Means multiplied by 7. SD imputed from Tapia-Haro 2000, as this was most similar study.
(11) Week 7.
(12) Day 19.
(13) RCT crossover. Mean difference was 1.6(10). The specific means for the intervention or control group were not provided.

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Figure 3. Forest plot of comparison—the Frequency of Attacks per Week in Non-Pharmacologic Intervention vs Control Groups for Primary and Secondary Raynaud's Phenomenon or Both Primary and Secondary.

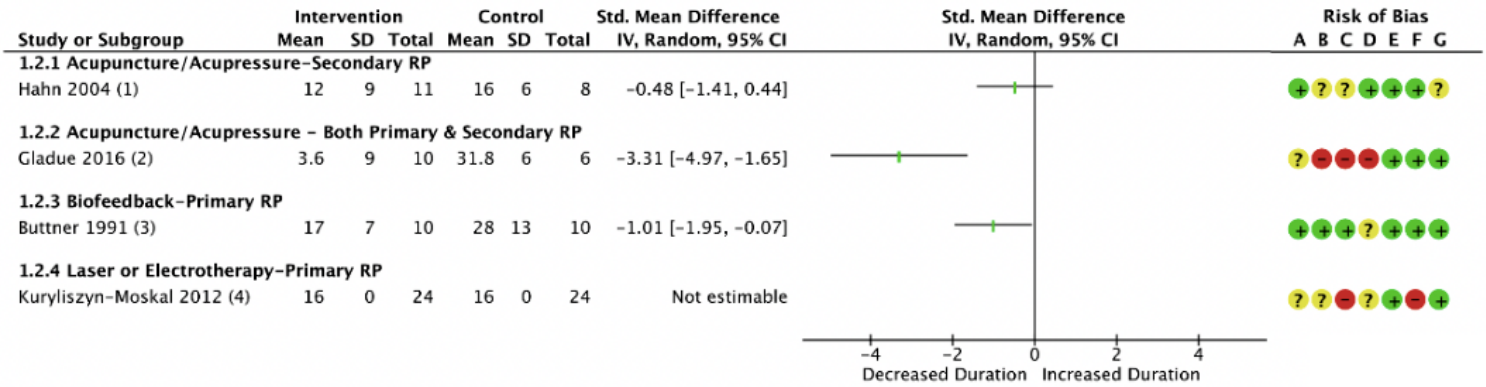
per day. Although Gladue et al.[29] did not use acupuncture as an NPI, they used two types of acupressure therapies, including vasodilation and relaxation acupressure. Their control group received an education package about Raynaud's. This study presented the combined data from the 2 acupressure groups and included both primary and secondary RP. The mean frequency of attacks in the acupressure versus control groups was 6.71 (11.9) versus 12.4 (7.7) at 8 weeks. The changes in baseline between the groups were not statistically significantly different (Figure 3).

Gladue et al.[29] also reported a reduction of 11.4 (19.9) minutes in the average duration of attacks in the acupressure groups versus an increase in the control group (0.8 [11.2]) from baseline. These changes and the difference between the groups were not statistically significant. Hanh et al.[28] similarly noted a statistically insignificant decrease in the mean duration of attacks before and after the acupuncture treatment (15[12] pre-treatment vs 12[9] post-treatment; Figure 4).

Gladue et al.[29] used a 0 to 100 visual analog scale (VAS) to measure pain and a patient VAS for the patient's assessment (0-10). There was a statistically significant reduction from the baseline VAS scores in the acupressure group (p=0.02; Figure 5). Wang et al.[30] also used a healthcare questionnaire developed in China to assess the efficacy of acupuncture with moxibustion for 15 days versus oral Betaloc tablets 50 mg twice a day for 15 days in primary RP. This criterion assessed symptoms resolution, tolerance to temperature, and nail fold microcirculation. The effective rate of the acupuncture group was statistically significantly higher than the control (x^2= 7.87; p<0.05).

Temperature Biofeedback

The Raynaud's Treatment Study Investigators[24] and Guglielmi et al.[31] compared skin temperature biofeedback with electromyography, whereas Sporbeck et al.[23] and Büttner et al.[32] used no treatment and hand exercises as control groups, respectively. These studies assessed primary RP; however, it is unclear if Sporbeck et al.[23] included secondary RP as well. The mean difference in the frequency of attacks per week for all the studies assessing primary RP ranged from -0.1 (-0.41, 0.22) to 0.48 (-0.4, 1.36) (Figure 3). The frequency of attacks per week was higher in the skin temperature biofeedback groups at 4[31] and 5 weeks[32] when compared to no treatment or hand exercises, respectively, but lower when compared to electromyography at 2 months.[24] The Raynaud's Treatment Study Investigators[24] noted up to a 32% reduction in attacks with biofeedback, but this was statistically insignificant. Büttner et al.[32] also reported a decrease in attacks from 4.8(2.9) to 3.4(2.1) in the biofeedback group and 3.9(1.9)



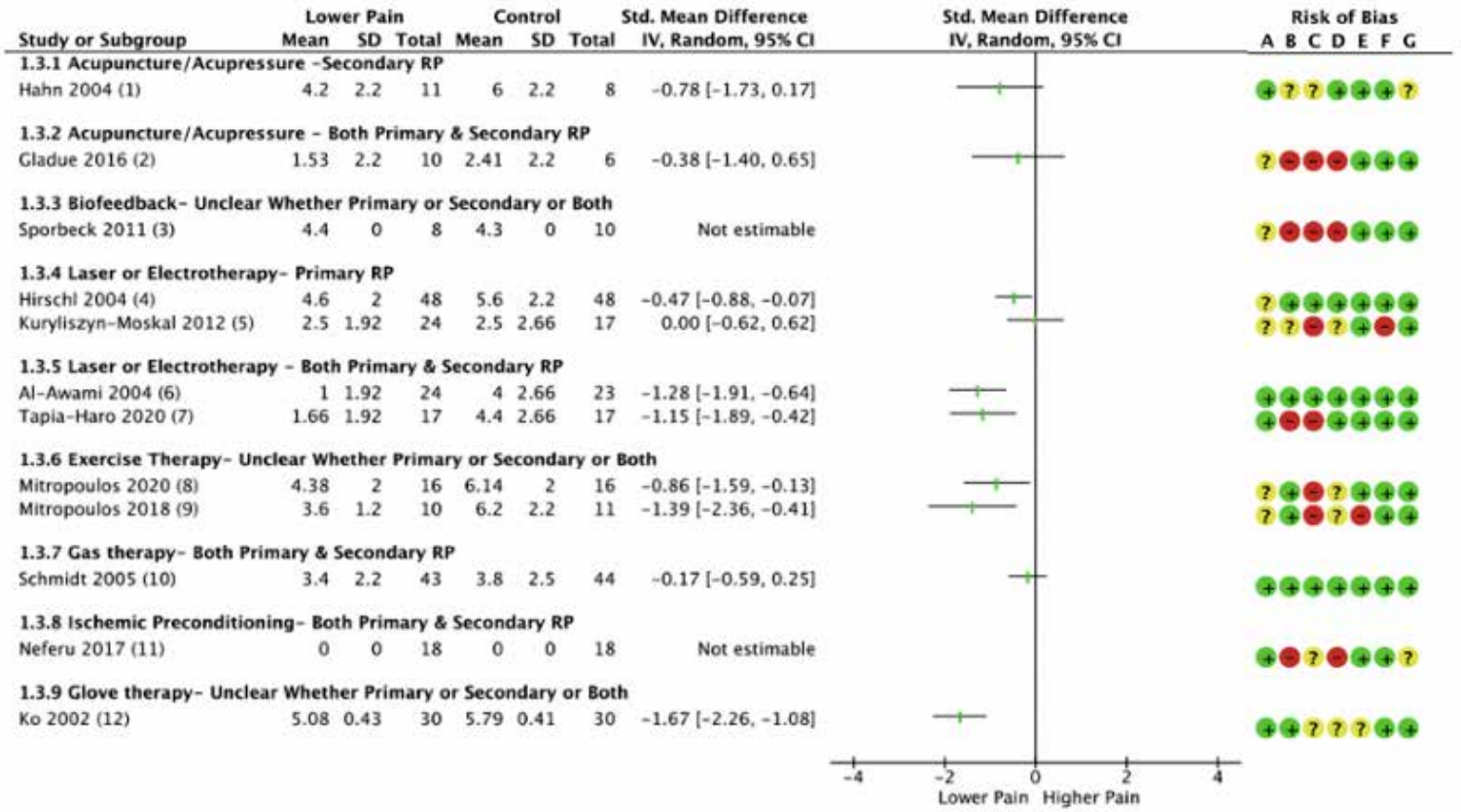
Footnotes
(1) Week 12.
(2) Week 8. The study only reports a change from baseline and baseline were not provided. Baseline values and SD imputed from Hahn 2004.
(3) Week 5.
(4) Week 3. Means were extracted from graphs.

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Figure 4. Forest plot of comparison—the Duration of Attacks (minutes) in Non-Pharmacologic Intervention vs Control Groups for Primary and Secondary Raynaud's Phenomenon or Both Primary and Secondary.

to 3.1(2.1) in the placebo group; however, the reductions in both groups were not statistically significant. Büttner et al.[32] also found that the duration of attacks was significantly lower in the biofeedback group compared to the control at 5 weeks post-treatment (Figure 3 and 4).

Sporbeck et al.[23] used the Scleroderma VAS to assess pain. The absolute change from baseline at 12 weeks in the biofeedback groups was -0.5 and +0.5 in the control group (extrapolated from a graph); p=0.094 between the two groups (Figure 5). The baselines were 4.9 (8.6) and 3.8 (7.5) for biofeedback versus control. The Raynaud's Treatment Study Investigators[24] also reported clinical ratings of improvement in RP assessed by physicians, which included the severity, the impact of RP, improvement, and general health. At 1 year, there was no significant difference between the biofeedback and control groups, 49(57) versus 49 (65), respectively.



Footnotes
(1) Week 12. Means and SD multiplied by 2. This study used a severity scale out of 5 (0: only 1-2 fingertips, 5: entire hand).
(2) Week 8. Means divided by 10 and subtracted from the baseline means. SD used from Hahn 2004. VAS scale was 0 to 100.
(3) Week 12. Change from baseline extrapolated from graphs. Extracted values were subtracted from baseline means.
(4) Week 12. Means multiplied by 2. VAS scale ranged from 0 to 5.
(5) Week 3. VAS scores extracted from graph. The values were divided by 10 (VAS 0 to 100 used). SD imputed from Tapia-Haro 2000.
(6) Week 6. SD imputed from Tapia-Haro 2000, as this was most similar with respect to the intervention and sample size.
(7) Week 7. VAS from pre-Cold stimulation test.
(8) Week 12. Means and SD scores multiplied by 2. 5-point scale was used.
(9) Week 12. Means and SD multiplied by 2. 5-point scale was used. We report arm cranking ergometer vs control.
(10) Day 19. Mean and SD divided by 10 to convert from mm to cm. Huskisson VAS (0 to 10 cm) uesd.
(11) RCT crossover. Mean difference between intervention and control groups was -0.4 (p=0.89).
(12) Week 12. Mean and SD divided by 10. VAS 0 to 100 used.

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel...
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Figure 5. Forest plot of comparison—Pain (0 to 10 scale) in Non-Pharmacologic Intervention vs Control Groups for Primary or Secondary Raynaud's Phenomenon or Both Primary and Secondary.

Lasers and Electrotherapy

The overall mean difference in the mean frequency of RP attacks per week between laser or electrotherapy and placebo groups in primary RP ranged from -0.36 (-0.76, -0.04) to 0 (-0.57, 0.57),[20,22,33] and -1.83 (-2.64, -1.01) to -1.65 (-2.32 to -0.98) in studies that combined primary and secondary RP[27,34] (Figure 3). Hirschl et al. (2002)[22] and Hirschl et al. (2004)[20] conducted RCT crossover studies on primary RP (n= 30 and 64 respectively) comparing low level laser therapy with placebo laser irradiation. Both studies used 200 mW lasers with either 685 nm[20] or 625 nm[22] wavelengths, and the placebos had wavelengths of either 640-685 nm[20] or 670 nm[22] for 3 to 5 sessions per week. In the 3rd week, the frequency of attacks per week was significantly lower (p=0.001) in the laser intervention compared to the control in Hirschl et al. (2004)[20] However, the differences between the two groups in 2002 were not statistically significant (p = 0.520) when comparing the relative frequency of attacks per week. Al Awami et al.[27] also compared laser therapy (40 mW, 670 nm) with a sham laser in primary and secondary RP combined and demonstrated statistically significantly lower frequencies in the intervention group at 6 weeks (p=0.007), 21 versus 35 attacks per week (Figure 3).

Similar to laser therapy, Tapia-Haro et al.[34] compared galvanic current electrotherapy (f 220–240V and 50/60+10% Hz) and conservative therapy (e.g., anti-inflammatory, vasodilatory and analgesic drugs and lifestyle recommendations) to conservative therapy alone, in primary and secondary RP (the results were combined). The electrotherapy resulted in statistically significantly fewer attacks per week compared to the control at week 7, 11.53(8.55) versus 27.17(8.16).

Kuryliszyn-Moskal et al.[33] further compared 2 groups receiving either laser bio-stimulation with a magnetic field (frequency 40 Hz, induction 1–5 mT, 10–20 min per session) or only laser bio-stimulation. In both groups, the participants received 3 weeks of pentoxifylline and 3 weeks of physiotherapy. After 3 weeks of laser or laser and magnetic field, both groups had roughly 12 attacks per week. Magnetic field therapy added no therapeutic benefit. In addition, this study did not find a significant difference in the duration of the attacks (Figure 4).

Three of the studies above consistently reported statistically significant lower VAS scores in the intervention group compared to the control from weeks 6 to 12.[20,27,34] Tapia-Haro et al.[34] reported a smaller mean difference between the intervention and control groups before and after a cold stimulation test, -2.74(0.8) versus -0.05(0.4) at 7 weeks. The overall mean difference in pain for primary RP and both primary and secondary RP respectively ranged from -0.47 (-0.88, -0.07) to 0 (-0.62, 0.62) and -1.28 (-1.91, -0.64) to -1.15 (-1.89, -0.42). Kuryliszyn-Moskal et al.[33] did not report a difference between their 2 groups (Figure 5).

Exercise Therapy

Mitropoulos et al. 2020[35] and 2018[25] both assessed the efficacy of exercise in treating RP; however, it is unclear whether these studies combined data for secondary and primary RP. The interventions included either a 12 week high-intensity interval training (e.g., arm crank warm-up, high intensity exercise, and light aerobic exercises)[35] or arm crank ergometer[25] (Figure 5). The control groups did not perform these organized exercises. Both studies reported pain outcomes (5-point scale) and minor outcomes, including life satisfaction scores out of 10. In both studies, the pain was statistically significantly lower after the exercise intervention compared to the control ($p<0.05$). The life satisfaction after exercise therapy was significantly higher than the control groups in 2020 and 2018, 9.25(0.9) versus 7.33(1.8) and 8.1(1.7) versus 4.9(1.5), respectively.

Other Therapies

Schmidt et al.[26] compared natural carbon dioxide gas therapy for 18 days to a control group receiving placebo gas for 9 days and COS for 9 days in patients with both primary and secondary RP. At day 19, there were no statistically significant differences in the frequency or severity of attacks between the 2 groups (Figure 4 and 5). The risk of bias for this study was low.

Ko et al.[36] described the use of ceramic impregnated "thermoflow" gloves, which include 95% polypropylene and polyethylene; 5% ceramic. These gloves supposedly absorb external ambient infrared radiation and reflect it into the underlying tissues. The control group received placebo gloves. At 12 weeks, the frequency of attacks significantly reduced from baseline (50.8[4.3] attacks per week; p=0.001) in the intervention group with no statistically significant difference in the control group (57.9[4.1]; p=0.2; Figure 3). This study also assessed the participant's subjective response to treatment using a Likert scale (1: markedly worse to 7: markedly improved). The intervention group

had a statistically significant higher score compared to the placebo (5.66 vs 4.13; p=0.001). This study has a low risk of bias overall, however, it is unclear how the participants and subjects were blinded.

Ischemic preconditioning for the treatment of primary and secondary RP was assessed by Neferu et al.[21] in a crossover trial. Compared to the control (sham preconditioning), ischemic preconditioning did not differ significantly in the frequency of attack (increased by 0.5[10]; p = 0.84), duration of attacks (decreased by 55.6[516.4] minutes; p = 0.66), and pain (decreased by 0.4[12.9] on VAS; p = 0.88). This study included both primary and secondary RP and combined the results.

The included studies inconsistently reported adverse side effects; 6 studies had mentioned side effects. Out of these studies, only Ko et al.[36] reported skin irritation in 3 participants, and the Raynaud's Treatment Investigators[24] reported a headache in 1 participant receiving biofeedback. There were no serious adverse events nor any withdrawals due to serious adverse events reported.

DISCUSSION

The main categories of NPIs identified included acupuncture and other needling techniques, skin temperature biofeedback, lasers and electrotherapy, exercise therapy, gas therapy, therapeutic gloves, and ischemic preconditioning. Generally, most of the studies demonstrated a trend towards therapeutic benefit for treating primary or secondary RP when assessing frequency, duration, and severity of attacks. However, there was substantial heterogeneity amongst the studies, including the timeframe of interventions and data collection, control groups, diagnostic methods for RP, population demographics, and characteristics of comparable interventions (e.g., differences in wavelengths for laser therapy). Overall, the studies had a low to moderate risk of bias with a few studies, including Sporbeck et al.,[23] the Raynaud's Treatment Investigators,[24] and Gladue et al.,[29] mainly due to concerns with blinding of participants or subjects.

Overall, laser therapy and electrotherapy had the largest pool of studies with consistent evidence compared to other NPIs. The risk of bias for these studies was low overall, with only Tapia-Haro et al.,[34] have a moderate-to-high risk of bias due to concerns with the blinding in the study. Al Awami et al.[27] had the lowest risk of bias; however, they did not differentiate the results between patients with primary or secondary RP. More than half (60%) of the studies reported significant reductions in frequency per week compared to the control, 40% of which included both primary and secondary RP. Most (75%) of the studies demonstrated a significant decrease in the severity/painfulness of attacks in both primary and secondary RP.

In the trials assessing the use of acupuncture, acupressure or warm needling therapies, there were generally no statistically significant reductions in the frequency or duration of attacks when compared to the control overall. Appiah et al.[11] showed a significant difference in the frequency of attacks in primary RP, but the control group received no treatment. Thus, there is a high possibility that the study participants and subjects were not blinded. Similarly, there is a moderate risk of bias for these studies as 2 studies have low risk, and 2 studies have high risk. The populations in these studies are also inconsistent, as only 2 studies included primary RP, one included secondary RP, and one study combined both types. Acupuncture is a time consuming and costly therapy; the current evidence does not justify its use over other interventions.[28]

With regards to temperature biofeedback, the data are inconsistent, and many studies were of low quality. All but 1 study included only primary RP, although it is unclear whether Sporbeck et al.[23] included both secondary and primary RP. Two studies reported a higher number of attacks in the biofeedback group compared to the control whereas, other studies reported a statistically insignificant decrease in the frequency of attacks. However, the duration of attacks was reported to be significantly lower by Büttner et al.[32] Temperature biofeedback seemed to have a statistically insignificant effect on the level of RP pain and physician's global assessment.

More recently, exercise therapy has been explored, showing strong statistical evidence. Two studies noted a marked decrease in pain and improvements in life satisfaction.[25,35] However, there is a moderate-to-high risk of bias for these studies as it is difficult to control for the level of baseline and ongoing physical activity amongst the subjects outside of the structured exercise programs. It is also likely difficult to blind the participants and subjects when the control group does not receive any form of structured exercise. It is also unclear from the inclusion criteria of both studies whether the participants had primary or secondary RP or both. In a similar sense, although Ko et al.[36] showed strong

statistical evidence supporting the therapeutic benefits of "thermoflow" gloves, further studies are required to replicate their findings. It is also unclear whether this study included both primary and secondary RP, as the "Pal criteria" was used for diagnosis. Thus, it is worthwhile to further explore the use of therapeutic gloves and exercise therapy moving forward, as these modalities are affordable and clinically realistic.

A previous review conducted by Malenfant et al.[37] in 2009 also reviewed complementary and alternative medicine in the treatment of RP. This review also found that high-quality evidence is limited, with biofeedback having the least consistent and supportive evidence. This study noted the efficacy of laser therapy, supported by our findings along with the addition of 2 new RCTs since 2009.

Nevertheless, due to the inconsistent and low-quality evidence on NPIs for RP, it is difficult to make clinically relevant decisions for patient care. Notably, some studies did not differentiate between primary and secondary RP when presenting the efficacy of NPIs.[21,23,26,27,29,34] This limits the generalizability of the results in a clinical setting as the management and prognoses of secondary and primary RP are different. Most of the studies did not discuss adverse events. Thus, further information is required to better understand the safety of NPIs, especially those that are more invasive such as acupunctures and lasers.

The predominance of RP in colder climates is reflected in the studies in this review; the majority took place in countries located in the Northern hemisphere. In addition, the participants of the studies were primarily sourced from clinics, making the results more generalizable to clinical settings with patients with comorbidities. For instance, the trial by the Raynaud's Treatment Study Investigators[24] was advertised to five clinics in different geographical areas and climates.

A limitation of this current review includes the exclusion of 5 articles[12,16-19] for which we had emailed the authors for clarification or could not translate (Junger et al.[16]). The NPIs being assessed in these studies included bathing with Chinese medicine, infrared sauna and relaxation therapy, and temperature biofeedback. For the purposes of this review and the forest plots, we used the SDs for major outcomes from similar studies assessing similar interventions with the SD was not provided or when only the change from baseline difference was provided. Thus, the data in the forest plots may not accurately reflect the studies. Some of the studies also included both secondary and primary RP and combined the results when presenting the data. This is a major limitation clinically, as the pathogenesis and treatment of primary and secondary RP differ. It is important to note that this review did not include studies assessing the therapeutic use of natural dietary adjuvants, supplements, extracts, smoking cessation or complementary medicine in treating RP.

CONCLUSION

In summary, the literature on the therapeutic efficacy and safety of the NPIs for the treatment of RP is limited and inconsistent. Although the studies included in this review trended towards decreased frequency, duration, and severity of RP attacks with the NPIs, many of these improvements were not statistically significant. We found that the laser and electrotherapy had the largest pool of studies and consistent evidence. Further high-quality and multi-center RCTs are required to make definitive clinical decisions when treating patients with RP with NPIs.

Conflict of Interest: None

Funding: University of Ottawa Journal of Medicine Research Assistantship

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Table 1. Study Characteristics of the Studies Assessing Non-Pharmacologic Interventions to Treat Raynaud's Phenomenon.

First author, Year	Study country	Design	Intervention	Comparator	Inclusion criteria	Exclusion criteria	Length of follow up	Primary outcome
Hahn, 2004	Germany	RCT	Acupuncture	Sham acupuncture	Diagnosis of secondary RP using the American Rheumatism Association Criteria		16 weeks	Frequency Duration Severity
Gladue*, 2016	US	RCT	Vasodilation acupressure (group A) and Relaxation acupressure (group B)	Education	> 18 years Diagnosis of primary or secondary RP Reported at least three attacks per week Had been on stable vasodilator medications for the previous 2 weeks Willing to comply with study visits and treatment plans	Patients with a history of stroke, myocardial infarction or life-threatening arrhythmia within the previous six months, uncontrolled hypertension (SBP > 140 mm Hg, DBP > 90 mmHg), significant digital ulcers or difficulty with hand dexterity limiting their ability to perform acupressure	8 weeks	Frequency Duration Severity
Appiah, 1997	Germany	RCT	Acupuncture	No treatment	18-60 years Diagnosis of primary RP No use of vasoactive drugs during the study and 6 weeks before	History of myocardial infarction or angina pectoris Pregnant	1 week 12 weeks 23 weeks	Frequency Duration Severity
Wang, 2003	China	RCT	Warm needling treatment	Betaloc tablets	Diagnosis of primary RP		15 days	Raynaud's condition score
Sporbeck, 2011	Germany	RCT	Skin temperature Biofeedback	Untreated vasculopathy	Diagnosed by American College of Rheumatology criteria for Systemic sclerosis and suffering from RP		4 weeks 12 weeks	Scleroderma-Visual Analog Scale (VAS) for Raynaud's phenomenon

Raynaud's Treatment Study Investigators**, 2000	US	RCT	Skin Temperature biofeedback	Electromyography	Diagnosis of primary RP History of 2 or more attacks per day during the previous cold season	Secondary RP	2 months	Frequency Physician's global assessment
Guglielmi, 1982	US	RCT	Skin temperature biofeedback	Electromyography	Diagnosis of RP Bilateral discoloration of the fingers precipitated by cold or emotional stimuli Absence of nutritional changes	Complicating organic disorders Evidence neurovascular syndromes Excessive swelling in extremities Skin changes typical of scleroderma or lupus erythematosus Pain in the joints or deformity of the fingers Hypertension Evidence of occupationally induced symptoms Taking medications known to cause vasospastic symptoms Taking medications for Raynaud's disease History of sympathectomy	Monthly (1 to 5 months)	Frequency Duration Severity
Buttner, 1991		RCT	Skin temperature biofeedback	Gymnastic hand exercises	Diagnosis of primary RP		5 weeks 3-week follow-up-post-treamt-ment	Frequency Duration
Hirschl, 2002	Austria	RCT cross-over	Low level laser therapy	Placebo laser	Diagnosis of primary RP		2 weeks	Frequency Severity
Hirschl, 2004	Austria	RCT cross-over	Low level laser therapy	Placebo laser	Diagnosis of primary RP Not currently taking vasoactive medication	Secondary RP	3 weeks 12 weeks	Frequency Severity

Kuryliszyn-Moskal, 2012	Poland	RCT	Laser bio stimulation with low frequency pulsed magnetic field	Laser bio stimulation	Diagnosis of primary RP		3 weeks	Frequency Duration Severity
Al-Awami, 2004	Austria	RCT	Low level laser irradiation	Placebo laser	Diagnosis of primary RP for 2 years or more and on average At least 4 episodes of RP per week	Under 18 years Over 65 years Women of childbearing age who were not using adequate contraception Patients with a history of severe cardiorespiratory or metabolic disorders	6 weeks 3 months	Frequency Duration Severity
Tapia-Haro***, 2020	Spain	RCT	Conservative treatment and galvanic current electrotherapy	Conservative treatment	>18 years Diagnosis of primary or secondary RP	Skin alterations (scars, gangrene or ulcers in the area to be treated) Upper limb entrapment syndrome Pregnancy or breastfeeding Tumoral process	7 weeks 15 weeks	Frequency Severity
Mitropoulos, 2020	UK	RCT	Exercise group (twice/week)	No physical activity	>18 years Diagnosed by American College of Rheumatology criteria for limited systemic sclerosis and suffering from RP Disease duration between 1 and 10 years Patients should be able to perform exercise	Advanced pulmonary arterial hypertension or interstitial lung disease Diagnosed with another inflammatory condition Patients presenting myositis, proximal muscle weakness Patients with New York Heart Association class 3 or 4 Current smokers or people who stopped smoking within 4 weeks of health screening Pregnant	12 weeks	Severity Quality of life

Mitropoulos, 2018	UK	RCT	Arm cranking ergometer (twice/ week)	No physical activity	Same as above	Same as above	12 weeks	Severity Quality of life
Schmidt****, 2005	France	RCT	Natural CO2 gas therapy	Placebo and natural CO2 gas therapy	Diagnosis of mild primary or secondary RP with synoptic phase as defined by the criteria of Allen and Brown	All other causes of RP (drug induced, toxic, traumatic, endocrine, vasculitis, and arterial disease other than atheroma)	12 weeks	Frequency
Ko, 2002	Canada	RCT	Ceramic-impregnated thermoflow gloves	Placebo gloves	>18 years Diagnosis of RP using the Pal criteria	Severe pulmonary disease Myocardial infarction Terminal cancer Pregnant	12 weeks	Severity Patient's response to treatment
Neferu, 2017	Canada	RCT cross-over	Ischemic preconditioning	Placebo	>18 years Diagnosis of RP 7 attacks per week sBP>80 mmHg Ability to provide consent and complete RP diary	New therapy in the 2 weeks prior sBP > 180 Previous non-compliance with treatments	8 weeks	Frequency Severity Patient's global assessment

*High dropout rate approaching 30 hypothesized to be due to the difficulty with keeping up the daily acupressure treatment or inefficacy

**85% of biofeedback and 83% of medication participants completed attack cards (for primary outcome); By 2 month follow up, 68% biofeedback and 82% medication completed attack cards

***Conservative treatment includes anti-inflammatory, vasodilatory and analgesic drugs, lifestyle recommendations (maintaining high core body temperature, avoidance of cold exposure, use of gloves and cessation of smoking, etc.)

****Control: 18 days of intervention; 9 days of placebo treatment followed by 9 days of CO2 gas therapy

Table 2. Population Demographics in the Studies Assessing Non-Pharmacologic Interventions to Treat Raynaud's Phenomenon.

Study	Sample size (n)		Primary Raynaud's		Secondary Raynaud's		Disease duration (years; SD)		Age (years; SD)		Sex (female)		Comments
	INT	COM	INT	COM	INT	COM	INT	COM	INT	COM	INT	COM	
Hahn, 2004	11	8			11	8			47± 12	41± 11	10	6	All secondary RP
Gladue, 2016	16	7	10	5	6	2			52.3 ± 16.1	44.3± 15.5	12	6	This study did not differentiate between primary or secondary RP when presenting the results.
Appiah, 1997	17	16	17	16			16.1± 14.6	11.4± 11.1	45.5± 11.5	41.5± 10.7	12	11	All primary RP
Wang 2003	30	30	30	30					26-58	24-57	21	23	All primary RP
Sporbeck, 2011	8	10					6	1.5	50± 15.1	58.9± 5.3	15	9	Unclear whether secondary and primary RP were combined
Raynaud's Treatment Study Investigators, 2000	81	74					12.3± 10.4	14.0± 11.1	44.1± 12.5	45.5± 11.7	109		70% of the total participants were women; all primary RP
Guglielmi, 1982	12	12	12	12			9.5± 7.42	11± 9.61	33.25± 9.62	33.83± 8.72			Duration is specified as "years since onset"; sex not specified; all primary RP
Buttner, 1991	10	10	10	10					35-59 (all subjects)		17 females, 3 males**		All primary RP
Hirschl, 2002	18						24± 16		53± 17		15		Crossover study, therefore, intervention and comparator had same population; all primary RP
Hirschl, 2004	48						20± 10		46± 14		38	38	Crossover study, therefore, intervention and comparator had same population. All primary RP

Kuryliszyn-Moskal, 2012	24	24					10.1 (1 to 30)*	11.0 (1 to 40)*	45.2 (19 - 66)*	37.4 (19-77)*			Sex not specified; all primary RP
Al-Awami, 2004	24	23	9	9	15	14	6 (3 to 13)*	13 (4 to 25)*	45 (36 - 53)*	46 (37 - 56)*	16	21	Both primary and secondary RP
Tapia-Haro, 2020	17	17	6	7	11	10	12.8± 10.5	12.8± 9.8	43.2± 18.1	43.5± 17.7	12	11	Duration is specified as "years since onset"; both primary and secondary RP
Mitropoulos, 2020	16	16					8± 2	8± 2	69.6± 11.4	63.6± 12.2	29**		Unclear whether secondary and primary RP were combined
Mitropoulos, 2018	10	11					7.8± 2.3	6.3± 2.0	69.1± 9.7	62.2± 14.3	31**		Unclear whether secondary and primary RP were combined
Schmidt, 2005	43	44	37	39	6	5	13.3± 10.9	14.4± 10.6	48.6± 14.4	48.8± 13.9	39	35	Both primary and secondary RP
Ko, 2002	30	30							54.1± 12.1	51.8± 12.3	20	26	Diagnosis of RP made using the “Pal criteria”
Neferu, 2017	18		1		17		13.9± 7.6		60.8± 9.4		16		Crossover study, therefore, intervention and comparator had same population; 5.6% were primary RP; included both secondary and primary RP

*Range
**# of participants in total sample size combined; not specified based on intervention versus comparison
INT: intervention; COM: comparison

SUPPLEMENTARY INFORMATION

Non-Pharmacological Interventions for the Treatment of Raynaud's Phenomenon: A Systematic Review

DOI for the original publication: https://doi.org/10.18192/uojm.v13i1.6175

Supplementary 1. Search Strategy used for Searching the Databases for Articles to be Screened

Embase Classic+Embase <1947 to 2021 June 08>
Ovid MEDLINE(R) ALL <1946 to June 08, 2021>
EBM Reviews - Cochrane Central Register of Controlled Trials <May 2021>

1. Raynaud Disease/ 13938
2. Vasospasm.ti,ab. 29094
3. raynaud$.tw. 20745
4. or/1-3 54027
5. Raynaud phenomenon/ 22400
6. vasospasm/ 10888
7. raynaud$.tw. 20745
8. or/5-7 39263
9. Randomized controlled trial/ 1195698
10. Controlled clinical study/ 463861
11. random$.ti,ab. 3961563
12. randomization/ 196576
13. intermethod comparison/ 272183
14. placebo.ti,ab. 874737
15. (compare or compared or comparison).ti. 1125316
16. ((evaluated or evaluate or evaluating or assessed or assess) and (compare or compared or comparing or comparison)).ab. 4165075
17. (open adj label).ti,ab. 196913
18. ((double or single or doubly or singly) adj (blind or blinded or blindly)).ti,ab. 708607
19. double blind procedure/ 187161
20. parallel group$1.ti,ab. 83969
21. (crossover or cross over).ti,ab. 294838
22. ((assign$ or match or matched or allocation) adj5 (alternate or group$1 or intervention$1 or patient$1 or subject$1 or participant$1)).ti,ab. 771565
23. (assigned or allocated).ti,ab. 992819
24. (controlled adj7 (study or design or trial)).ti,ab. 1077946
25. (volunteer or volunteers).ti,ab. 525254
26. human experiment/ 547398
27. trial.ti. 932808
28. or/9-27 10300096
29. (random$ adj sampl$ adj7 (cross section$ or questionnaire$1 or survey$ or database$1)).ti,ab. not (comparative study/ or controlled study/ or randomi?ed controlled.ti,ab. or randomly assigned.ti,ab.) 17795
30. Cross-sectional study/ not (randomized controlled trial/ or controlled clinical study/ or controlled study/ or randomi?ed controlled.ti,ab. or control group$1.ti,ab.) 631245

31. (((case adj control$) and random$) not randomi?ed controlled).ti,ab. 36052
32. (Systematic review not (trial or study)).ti. 330017
33. (nonrandom$ not random$).ti,ab. 33813
34. Random field$.ti,ab. 5461
35. (random cluster adj3 sampl$).ti,ab. 2526
36. (review.ab. and review.pt.) not trial.ti. 1839156
37. we searched.ab. and (review.ti. or review.pt.) 71186
38. update review.ab. 277
39. (databases adj4 searched).ab. 80917
40. (rat or rats or mouse or mice or swine or porcine or murine or sheep or lambs or pigs or piglets or rabbit or rabbits or cat or cats or dog or dogs or cattle or bovine or monkey or monkeys or trout or marmoset$1).ti. and animal experiment/ 1110527
41. Animal experiment/ not (human experiment/ or human/) 2335916
42. or/29-41 5170036
43. 28 not 42 9425482
44. 8 and 43 5675
45. Raynaud Disease/ 13938
46. Vasospasm.ti,ab. 29094
47. raynaud$.tw. 20745
48. or/45-47 54027
49. randomized controlled trial.pt. 1054307
50. controlled clinical trial.pt. 186338
51. randomized.ab. 1884668
52. placebo.ab. 839620
53. clinical trials as topic.sh. 229494
54. randomly.ab. 1111443
55. trial.ti. 932808
56. or/49-55 4090332
57. exp animals/ not humans.sh. 34135393
58. 56 not 57 2637796
59. 48 and 58 2745
60. 8 use cctr 1753
61. 44 use emczd 3864
62. 59 use medall 1275
63. 60 or 61 or 62 6892

Supplementary 2. Methods Pertaining to a Meta-Analysis in our Protocol

Data Synthesis

We will undertake meta-analyses only where this is clinically meaningful do so. We will use fixed-effect models for combining data from studies where we are confident that the studies are estimating the same treatment effect: i.e., where trials are examining the same interventions and trials' populations and methods are sufficiently similar. Where studies may be estimating different treatment effects (i.e., due to different mechanisms of action of interventions), we will use random effects models for the meta-analysis. The primary analysis for our reviews for self-reported outcomes (e.g., pain and participant global assessment) will be restricted to trials with low risk of detection and selection bias.

If a meta-analysis cannot be conducted due to heterogeneity amongst the included articles, the values (e.g., means and standard deviations) of major outcomes will be presented in forest plots without a total. The major outcomes and findings of each category of NPI will be discussed and the range of mean differences will be reported when necessary for major outcomes. The articles will be reviewed narratively discussing the NPI, the patient population, and whether the major outcomes are statistically significant.

Data Analysis and Meta-Analysis

Dichotomous Data
Dichotomous outcomes will be presented as summary risk ratios with 95% confidence intervals. In the case of rare events (<10%), the Peto odds ratio will be reported. We will calculate the number needed to treat to benefit (NNTB) from the control group event rate and the risk ratio using the Visual Rx[38] NNT calculator.

Continuous Data
Continuous outcomes measured in the same way between trials will be pooled as mean difference (MD) with the corresponding 95% confidence intervals.

When different scales are used to measure the same outcome, standardised mean differences (SMD) will be calculated, with the corresponding 95% CI. SMDs will be back-translated to a typical scale (e.g., 0 to 10 cm visual analogue scale for severity) by multiplying the SMD by a typical among-person standard deviation (e.g., the standard deviation of the control group at baseline from the most representative trial) (as per Chapter 12 of the Cochrane Handbook).[39]

Unit of Analysis Issues

The unit of analysis for each outcome will be the participant. Where multiple trial arms are reported in a single trial, we will include only the relevant arms. If two comparisons are combined in the same meta-analysis, we will halve the control group to avoid double-counting.

Cross-over trials will be assessed to determine if it is likely that there is a problem with a carry-over effect, taking into consideration the type of intervention and the length of the washout period. If this is deemed a concern, then only first-phase data from cross-over trials will be included. When data from both periods of the cross-over trial are available, we will follow the methods described in Ch.16.4 of the Handbook[40] and consult with a statistician to ensure the analysis is performed correctly.

Assessment of Heterogeneity

Clinical and methodological diversity will be assessed in terms of participants, interventions, outcomes, and study characteristics for the included studies to determine whether a meta-analysis is appropriate. This will be conducted by

observing this data from the data extraction tables. Statistical heterogeneity will be assessed by visual inspection of the forest plot to assess for obvious differences in result between the studies and using the I-squared and chi-squared test.

As recommended in the Cochrane Handbook[41], the interpretation of an I-squared and chi-squared value of 0% to 40% might 'not be important'; 30% to 60% may represent 'moderate' heterogeneity; 50% to 90% may represent 'substantial' heterogeneity; and 75% to 100% represents 'considerable' heterogeneity. As noted in the Handbook, we will keep in mind that the importance of I^2 depends on (i) magnitude and direction of effects and (ii) strength of evidence for heterogeneity.

The chi-squared test will be interpreted where a P value ≤ 0.10 will indicate evidence of statistical heterogeneity.

If we identify substantial heterogeneity, we will report it and investigate possible causes by following the recommendations in section 9.6 of the Handbook.

Assessment of Reporting Biases

For meta-analyses with 10 or more studies, we will assess for reporting bias (publication bias) by inspecting for asymmetry in funnel plots as is recommended.[42,43] Where publication bias is detected, we will follow the recommendations in the *Cochrane Handbook for Systematic Reviews of Interventions*[44] to explore possible reasons.

Subgroup Analysis and Investigation of Heterogeneity

We plan to carry out the following subgroup analyses for each review when there is sufficient data:
1. by RP type (primary or secondary).
2. by intervention type.

Subgroup analyses will be limited to the major outcomes.

We will use the formal test for subgroup interactions in RevMan[15] and will use caution in the interpretation of subgroup analyses as advised in section 9.6 of the Handbook.[45] The magnitude of the effects will be compared between the subgroups by means of assessing the overlap of the confidence intervals of the summary estimated. Non-overlap of the confidence intervals indicates statistical significance.

Sensitivity analysis

We will perform sensitivity analyses to explore the robustness of the results of the major outcomes, stratified on the following factors when there is sufficient data:
1. trial quality - trials at low risk of bias for allocation concealment and blinding of outcome assessor
2. trial duration
3. diagnostic inclusion criteria used in the trial
4. time of the year trial was performed
5. estimations or imputations of standard deviations or correlation coefficients from cross-over studies

Results from these exploratory analyses will be interpreted with caution

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Yannick Galipeau & Bryce Bogie
Co-Editors in Chief
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Appel De Soumissions

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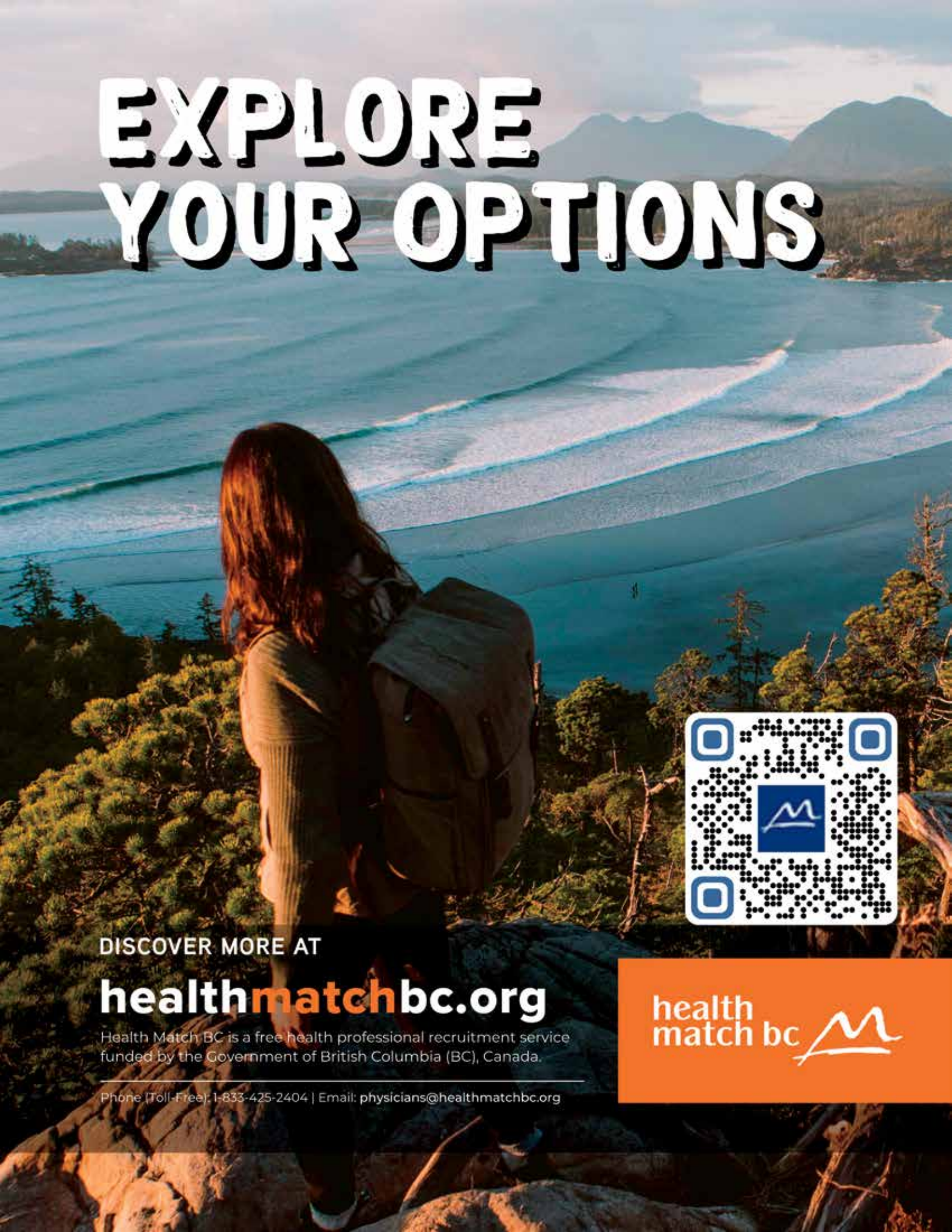
Yannick Galipeau et Bryce Bogie

Co-éditeurs en chef

Journal médical de l'Université d'Ottawa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