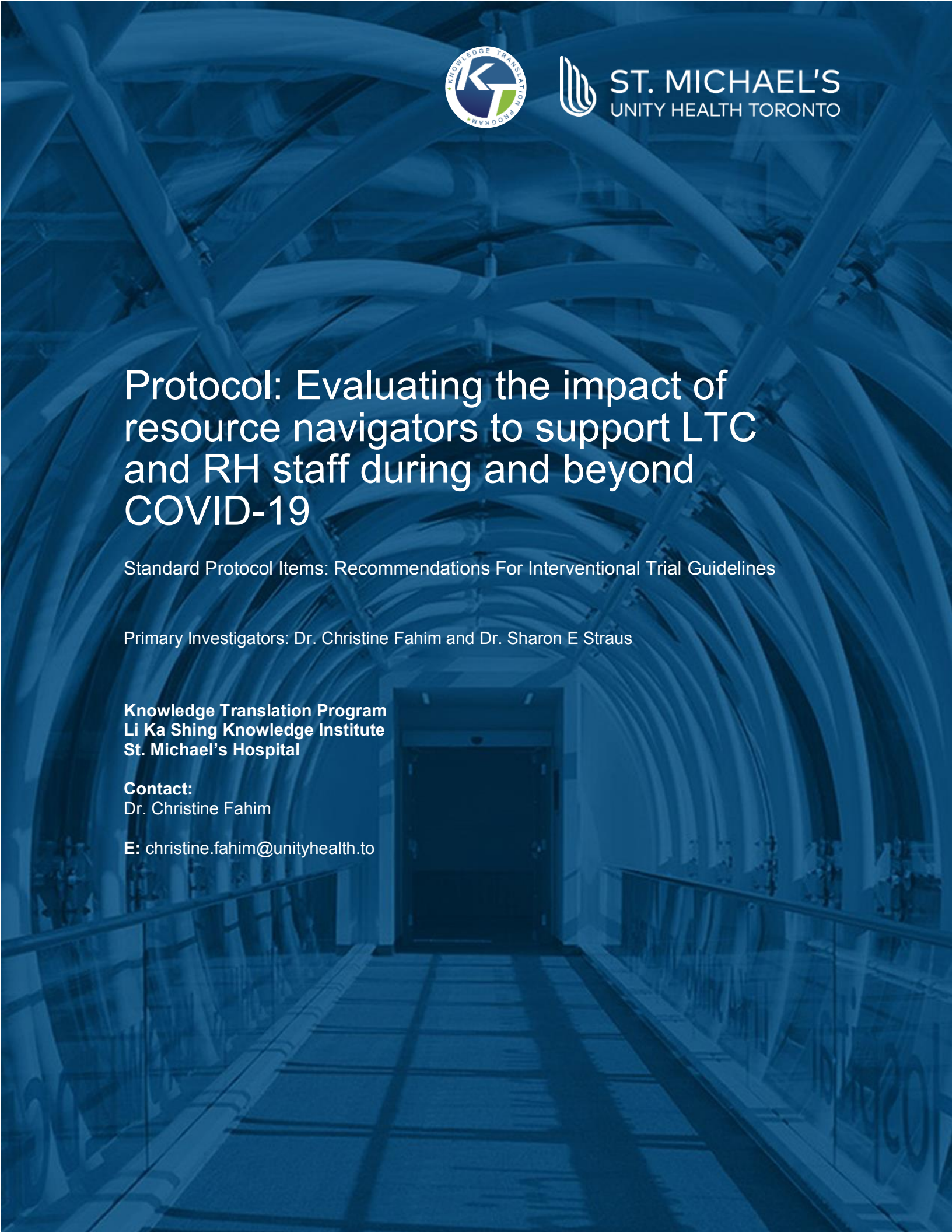

Protocol: Evaluating the impact of resource navigators to support LTC and RH staff during and beyond COVID-19

Standard Protocol Items: Recommendations For Interventional Trial Guidelines

Primary Investigators: Dr. Christine Fahim and Dr. Sharon E Straus

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1.0 Administrative Information

The following protocol outlines the details of this randomized controlled study following guidance from the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT). [1]

1. Title

Evaluating the impact of resource navigators to support Long-Term Care and Retirement Home Staff during and beyond COVID-19.

2. Trial Registration

2a: Registry

This study will be registered on clinicaltrials.gov.

2b: Data Set

Items from the World Health Organization Trial Registration data set will be included and updated once the study is registered in clinicaltrials.gov.

Data category	Information
Primary registry and trial identifying number	-
Date of registration in primary registry	-
Secondary identifying numbers	-
Source(s) of monetary or material support	Canadian Institutes of Health Research (CIHR) – Operating Grant University of Toronto Temerty Faculty of Medicine - Knowledge Translation Grant
Primary sponsor	KT Program, St. Michael's Hospital, Unity Health Toronto
Secondary sponsor(s)	-
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Contact for scientific queries	Christine (Tina) Fahim, PhD, MSc Christine.fahim@unityhealth.to 1-416-360-4000 ext 77300
Public title	Evaluating the impact of resource navigators to support Long-Term Care and Retirement Home staff during and beyond COVID-19
Scientific title	Evaluating the impact of resource navigators to support Long-Term Care and Retirement Home staff during and beyond COVID-19
Countries of recruitment	Canada
Health condition(s) or problem(s) studied	Long-term care and retirement home staff wellness

Intervention(s)	Control: educational resources Comparator: 1:1 tailored support from a resource navigator + educational resources
Key inclusion and exclusion criteria	Inclusion Criteria Age requirement: ≥18 years Employment status requirement: full-time or part-time PSW or other Long-term care and retirement home support staff employed in an Ontario Long-term care and retirement home Language requirement: English Technological requirement: email access Exclusion Criteria Not employed as a PSW or other support service staff in an Ontario Long-term care home; uncomfortable speaking or reading English; lack of email access
Study type	Interventional Allocation: randomized Intervention model: parallel assignment Masking: non-blinded Primary purpose: prevention & management Phase IV
Date of first enrolment	Not yet enrolling
Target sample size	154 (77 participants per arm)
Recruitment status	Not yet recruiting
Primary outcome(s)	Long-term care home staff wellness
Key secondary outcomes	Long-term care and retirement home staff burnout, knowledge of, access to and use of wellness supports; SARS-CoV-2 infection; rate of SARS-CoV-2 vaccinations; hospitalizations; and deaths

3. Protocol Version

Issue date: September 07, 2022

Protocol amendment number: 0

Authors: Dr. Christine Fahim, Dr. Sharon E. Straus, Dr. Stefan Baral, Dr. Adrienne Chan, Dr. Linn Holness, Dr. Sharmistha Mishra

4. Funding

This study is funded by the Canadian Institutes of Health Research (CIHR) – Operating Grant and the University of Toronto Temerty Faculty of Medicine - Knowledge Translation Grant. The educational resources and online repository that will be used for this study were developed through funding from the COVID-19 Immunity Task Force (CITF), the Ontario Ministry of Labour Training and Skills Development (MOLTSD) and the Canadian Immunization Research Network (CIRN).

5. Roles & Responsibilities

5a: Contributorship

(CF) Dr. Christine Fahim, Unity Health Toronto, St. Michael's Hospital, Li Ka Shing Knowledge Institute, 7th Floor, East Building, 209 Victoria Street, Toronto Ontario M5B 1T8, Canada

(SES) Dr. Sharon E. Straus, Unity Health Toronto, St. Michael's Hospital, Li Ka Shing Knowledge Institute, 7th Floor, East Building, 209 Victoria Street, Toronto Ontario M5B 1T8, Canada

(SB) Dr. Stefan Baral, Johns Hopkins- Bloomberg School of Health, E7146, 615 North Wolfe Street Baltimore Maryland 21205, United States

(AC) Dr. Adrienne Chan, Sunnybrook Health Sciences, 2075 Bayview Avenue, Toronto, Ontario, M4N 3M5

(DH) Dr. Dorothy Linn Holness, Division of Occupational Medicine, St Michael's Hospital, 30 Bond St, Toronto Ontario M5B 1W8, Canada

(SM) Dr. Sharmistha Mishra, Division of Infectious Diseases, St. Michael's Hospital, University of Toronto, 30 Bond Street, Toronto Ontario M5B 1W8, Canada

(BP) Dr. Ba' Pham, Unity Health Toronto, St. Michael's Hospital, Li Ka Shing Knowledge Institute, 7th Floor, East Building, 209 Victoria Street, Toronto Ontario M5B 1T8, Canada

(ID) Ian DaSilva, Ontario Personal Support Workers Association, 101 Holiday Inn Drive, PO Box 29045, Cambridge, Ontario N3C 0A0

(MF) Miranda Ferrier, Ontario Personal Support Workers Association, 101 Holiday Inn Drive, PO Box 29045, Cambridge, Ontario N3C 0A0

CF and SES conceived of the study. CF, SES, SB, AC, DH, and DM initiated the study design and implementation. BP provided statistical expertise in clinical trial design and will conduct the

primary statistical analysis. All authors contributed to refinement of the study protocol and will support and approve the final manuscript.

5b: Sponsor Contact Information

Trial Sponsor: Unity Health Toronto, St. Michael's Hospital, Li Ka Shing Knowledge Institute

Sponsor's Reference: N/A

Contact name: Drs. Sharon Straus and Christine Fahim

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Telephone: 416-864-3068 and 416-3604000 ext: 77300

Email: sharon.straus@utoronto.ca and christine.fahim@unityhealth.to

5c: Sponsor and Funder

The sponsor-investigators (CF, SES) developed the study design and will be involved in the analysis and interpretation of implementation data, manuscript preparation, and dissemination of results. The funding sources had no role in the design of this study and will not have any role during its execution, data analysis, interpretation of the data, or decision to submit results.

5d: Committees

A project steering committee with stakeholders will be established and will support study recruitment, monitoring, and the dissemination of study results. All data collection tools will be reviewed by the steering committee for acceptability, clarity of language and feasibility of format (e.g., mobile friendly access).). An honorarium will be provided for up to 6 long-term care and retirement home support staff who agree to take part in our steering committee. Steering committee members will be compensated for their time and contribution to steering committee meetings and any feedback they provide on project activities. We use the CIHR Strategy for Patient Oriented Research (SPOR) compensation framework for knowledge users to guide this [2].

Introduction

6. Background and Rationale

6a. Background And Rationale

More than 80% of the people who have died of COVID-19 in Canada lived or worked in long-term care homes and assisted living facilities.[3] Almost 60% of long-term care home staff are personal support workers (PSWs), who provide over 90% of direct resident care.[4-6] PSWs' essential, frontline work places them at increased risk of SARS-CoV-2 infection.[6] Additionally, PSWs are an unregulated workforce who are underpaid and undervalued.[4-6,8] Lack of workplace protections, constant fear of contracting or transmitting the SARS-CoV-2 virus, and longstanding systemic inequities can impact the overall wellness of PSWs and place them at increased risk of burnout and other challenges.[9-11] In addition, other long-term care and assisted living staff including those in nutrition and environmental services provide direct care and support for the residents that has been critical during the pandemic. These groups have similarly been affected by the pandemic and their needs have not been adequately met.[12]

In response to this, the Knowledge Translation Program (KTP) at St. Michaels Hospital launched efforts to support PSWs. Via in-depth discussions and surveys, >200 PSWs were canvassed to identify their needs during the pandemic. Four areas of need were identified, which included supports for:

1. Wellness, burnout and mental health
2. Infection Prevention and Control (IPAC)
3. Wraparound resources (e.g., access to food banks, caring for a family member with COVID-19) and
4. Vaccine information

Additionally, using the Theoretical Domains Framework, the KTP identified the following barriers that impact PSWs' and/or other long-term care and retirement home staff's ability to navigate the pandemic [13]:

- lack of knowledge of available resources
- perceptions of identity within the long-term care home context, resource challenges (e.g., lack of occupational health programs), and
  impact of social influences on beliefs (e.g., family and peer perceptions of vaccine efficacy and safety).

These barriers were mapped to corresponding implementation strategies via the Behaviour Change Wheel framework to identify education and enablement (e.g., supporting individuals' own self-efficacy) as interventions to mitigate the identified barriers.[13] Utility of these interventions was confirmed by our long-term care home staff partners and the Ontario PSW Association (OPSWA, who support >50,000 members), who believed routine check in calls

would reduce social isolation and support PSWs and other long-term care staff to find and use available resources to address their needs.[13]

Through funding from the COVID-19 Immunity Task Force (CITF), the Ontario Ministry of Labour Training and Skills Development (MOLTSD) and the Canadian Immunization Research Network (CIRN), the KTP developed educational resources compiled in a single online repository for long-term care home staff on optimizing infection prevention and control (IPAC) [14-17] in long-term care home, promoting wellness and preventing burnout [18,19] providing 'wraparound' [20, 21] resource supports to individuals (e.g., access to food banks, resources on self-isolation, caring for a family member with COVID-19), and addressing SARS-CoV-2 vaccine [22-24] myths and questions (via infographics and town halls created in partnership with OPSWA).[25, 26]

However, currently long-term care and retirement home staff access these resources passively and many do not have the capacity or skills to implement the resources effectively. A navigator is the missing link to putting these resources into practice.

Research Question

Through this clinical trial, we aim to answer the following research question:

What is the impact of tailored 1:1 support from a resource navigator and educational resources (intervention arm) compared to educational resources only (control arm) on the wellness of long-term care and retirement home staff *(primary outcome), burnout, knowledge of, access to and use of wellness resources, SARS-CoV- 2 vaccination status, self-reported SARS-CoV-2 infection and hospitalization (secondary outcomes).*

6b. Choice of Comparators

Aligning with the findings and work completed to date, a resource navigator for long-term care and retirement home staff was identified as a missing link to putting educational resources into practice. This was selected as our choice of comparator for the purposes of this study and identified needs.

7. Objectives

The aim of this study is to implement and evaluate the impact of implementing resource navigation for long-term care and retirement home staff in enhancing the uptake of available resources. For the purposes of this study, long-term care and retirement home staff will refer to PSWs and other support workers (including those who provide direct resident care or support

resident care through ancillary services such as nutrition, housekeeping and laundry) in long-term care and retirement home settings. To achieve our study aim we will:

1. Conduct a trial, which will randomize PSWs and other support service staff to receive 6 months of tailored 1:1 support from a resource navigator and educational resources (intervention arm) versus educational resources only (control arm) to navigate the pandemic.
2. Evaluate the impact of the intervention on PSW's and other support service staff's wellness (primary outcome), burnout, knowledge of, access to and use of wellness resources, alignment of provincial public health guidelines related to SARS-CoV-2 vaccine outcomes, SARS-CoV-2 infection, hospitalization, and death (secondary outcomes).
3. Conduct a process evaluation to assess quality and delivery of the study intervention.

8. Trial Design

This study is designed as a non-blinded, randomized controlled trial with long-term care and retirement home staff with two parallel groups to identify the impact of tailored 1:1 support from a resource navigator and educational resources compared to the use of educational resources only to navigate the SARS-CoV-2 (COVID-19) pandemic and beyond. Randomization will be performed using computer software to generate a 1:1 allocation sequence.

Methods: Participants, Interventions, Outcomes

9. Study Setting

This study will take place in Long-Term Care and Retirement Homes in Ontario. Long-term care homes are defined as residences where older adults can live and receive support with daily living. Long-term care homes also provide 24-hour nursing, primary medical and personal care. [27] Retirement homes are privately-owned residence that provides rental accommodation with care and services for seniors who can live independently with minimal to moderate support and are able to fund this lifestyle on their own [28]. Long-term care homes are funded by the provincial government and are regulated under the Long-Term Care Homes Act, 2007. In Ontario, there are 626 long-term care homes with 58% privately owned homes, 24% are non-for-profit, and 16% are municipal. Long-term care and retirement homes will be selected for the clinical trial by type, including privately owned, non-for-profit, and municipal. [29] This study will build on the existing partnerships of another KTP project, the Wellness Hub. The Wellness Hub project contains a network of 70 long-term care home who will all be eligible for participation in this study [29].

10. Eligibility Criteria

Inclusion Criteria

Participants eligible for the trial must meet the following criteria at randomization:

1. A fulltime or part-time employee aged 18 years and older identified as a Long-Term Care and Retirement Home staff (PSW's and other support service staff in those in nutrition, housekeeping and laundry) [12];
2. Work in an Ontario Long-term care or retirement home;
3. Comfortable speaking and reading English; and
4. Access to and willingness to use email for study communications

Exclusion Criteria

Participants will not be eligible to participate in the study if they:

1. Do not identify as or are not employed as a PSW and other support service staff;
2. Do not work in an Ontario long-term care or retirement home; and
3. Uncomfortable speaking or reading English.
4. Do not have access to or unwillingness to use email for study communications

A resource navigator will perform the study intervention. While the navigator will not directly provide counselling or mental health supports, they will serve as a liaison to link the PSWs and other long-term care and retirement home support service staff to these supports. The navigators will hold a degree or diploma in social services/work, psychology or a related field and have at least 2 years experience in these sectors..

11. Interventions

11a. Interventions

Each month, participants in the intervention arm will receive a PDF package by email from a research staff member, which will include wellness, burnout and mental health resources (e.g., how to use the free, self-referral Centre for Addiction and Mental Health service [18]; tips on reducing/preventing burnout [21]), SARS-CoV-2 vaccine infographics [22], a wraparound [20] resource package, and IPAC [17] tips/guidance. Participants that indicated they would like a print copy of the resources in the pre-screening survey (Appendix C) will be provided a copy via mail. Participants will also receive two hours (2, 1-hour sessions) of navigation support sessions from the resource navigator (by phone/zoom) per month for six months (Total 12, 1-hour sessions). While the resource navigator will not directly provide counselling or mental health supports, they will serve as a liaison to link the PSWs and other support service staff (where applicable) to these supports. The resource navigators will hold a degree or diploma in social services/work, psychology or a related field and have at least 2 years of experience in these sectors.

In the control arm, participants will receive the monthly educational resources only.

Both intervention and control arms will complete a baseline survey, exit survey (at 6 months) and interview if selected to participate

11b. Modifications

Participants may be inconvenienced by taking part in components of the study (e.g., exit interviews). The COVID-19 pandemic is also a stressful situation to many; therefore, risks will be mitigated by ensuring participants are aware that they have the option to participate and/or not answer any questions they do not wish to answer. Participants will be able to withdraw from the study at any point with no consequences by notifying a study coordinator, investigator or the resource navigator. Participants may have to withdraw due to end of employment or personal concerns. Preliminary sample size estimations have been calculated to account for participant attrition.

11c. Adherence

To facilitate adherence to the intervention, participants in the intervention arm will receive a package that includes educational resources by email and/or mail each month. Resource navigators will directly reach out to participants in the intervention arm (via email/phone) and will provide them with two hours of navigation support sessions (by phone/zoom) per month for six months. Additionally, during the course of the intervention, the resource navigation will also identify processes to enhance adherence for the six-month period through various methods including personalization of sessions (participant's communication and time preference) and providing ambient information pre-session (session reminders, goal of each session).

11d. Concomitant Care

Due to the nature of this study, all participants will be assessed if they are receiving other interventions related to wellness, which can be self-directed or organization directed. This will also enable the identification co-intervention bias, which can impact on the study outcome

12. Outcome Measures

1. Primary Outcome Measures

The primary outcome for this study is the impact of the intervention on staff wellness. This will be measured by determining the impact of resource navigation on the change in wellness between the 6-month time point and baseline for those who received educational resources and resource navigation compared to those who received educational resources alone.

Participant wellness will be assessed using the Personal Wellbeing Score.[31] The Personal Wellbeing Score measure was selected to align with the World Health Organization's 2004

definition of wellness: “the optimal state of health of individuals and groups. There are two focal concerns: the realization of the fullest potential of an individual physically, psychologically, socially, spiritually, and economically, and the fulfilment of one’s role expectations in the family, community, place of worship, workplace and other settings.” p.5, World Health Organization [32]

The Personal Wellbeing Score is a short, 4-item measure that takes a few minutes to complete. These features increase accessibility and reduce participant burden compared to longer wellness assessment tools. The scale has good internal reliability (Cronbach’s α =0.90) and correlates with health status (r=0.58) and health confidence (r=0.60[).[31] The analysis will use mean Personal Wellbeing Scores of participants and will be conducted at baseline and 6-months post-intervention.

2. Secondary Outcome Measures

Secondary outcome measures will include burnout, knowledge, access to and use of wellness supports, vaccination status, SARS-CoV-2 infection, hospitalization, and death. All measures will be assessed through a baseline and exit survey (at the 6-month time point) that includes the Personal Wellbeing Score.

Burnout will be assessed with the 22-item Maslach Burnout Inventory for Medical Personnel. [33] This measure takes approximately 10 minutes to complete, demonstrates good reliability and validity, has been tested among diverse stakeholder populations including PSWs, and tests for relevant domains (e.g., emotional exhaustion). [33-36] To assess knowledge, access to and use of wellness supports, Likert scale questions directly related to outcomes will be developed.

Demographic information will also be collected, and questions will be developed using the PROGRESS-Plus framework. [37] The PROGRESS-Plus framework will assess characteristics such as place of residence, race/ethnicity/culture/ language, occupation, gender, sex, religion, education, socioeconomic status, and social capital) to determine effects on the study outcomes.

Via participants’ Ontario Health Insurance Plan (OHIP) number, we will link to the ICES provincial administrative database to obtain participants’ vaccine status, and rates of SARS-CoV-2 infection, hospitalization and death, over the study period.[38, 39]. Unique to the exit survey, study participants will be asked about their satisfaction with the intervention. A process evaluation will be conducted to assess quality and delivery of the study intervention. The resource navigator will track the number, duration and focus of the 1:1 sessions per participant at the end of each individual session using a Process Evaluation- Intervention Tracking Form (Appendix Q). Participant experiences, suggestions for improvement and planning for sustainability will be collected via individual interviews with the resource navigator. A sample of

control (n=8-10) and intervention (n=8-10) participants will be interviewed. We will purposively sample the group, with an aim to reflect diversity in gender, age, race and other PROGRESS-plus characteristics

13. Participant Timeline

As noted above, the primary and secondary outcomes will be assessed using a multi-measure baseline and exit survey. Baseline surveys will be conducted 0-30 days after randomization and exit surveys will be conducted at 6 months (182 days) after the randomization date.

Process evaluation data will be collected throughout the duration of the intervention (from 0 days after randomization until the end of intervention (182 days)).

Post-intervention exit interviews will then be conducted at approximately 6-7 months (182-213 days) after the randomization date. These interviews will include a subsample of 8-10 participants from the intervention arm and 8-10 participants from the control arm of the study. See Figure 1 for flow of participants. Note: this will be a rolling recruitment.

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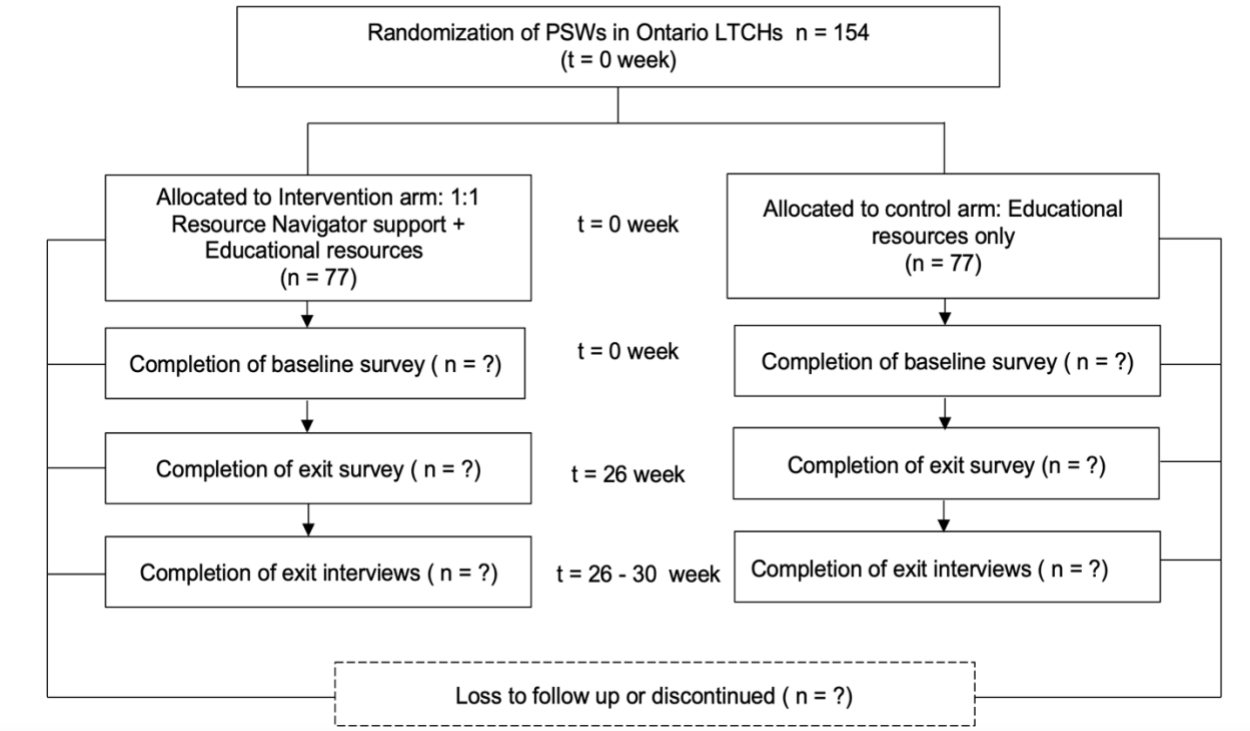
Figure 1. Flow of Participants



14. Sample Size

This study estimates that the standard deviation (SD) across mean Personal Wellbeing Scores is 10.2.[31] Assuming we will use a t-test to compare the scores across the intervention groups, a medium effect size of 0.5, a SD estimate of 10.2, a false positive error rate of 5% and a power of 80%, the estimated sample size is 64 participants per arm or 128 for the two arms. Including a buffer for participation attrition of 20%, the study will require a total of 154 participants (77 per arm).

15. Recruitment

The study team will be using multiple recruitment strategies: circle of contacts, snowball, and advertisements (Appendix A, B,Y). The study team will also leverage partnerships with OPSWA, Ontario LTC Association (OLTCA), Family Councils Ontario (FCO), and other Long Term Care and retirement organizations to recruit PSWs and other service support staff working in Ontario long-term care and retirement homes. All interested potential participants will be provided with a pre-screening survey to determine eligibility, the study information sheet and a consent form..

Methods: Assignment of Interventions (for controlled trials)

16. Allocation

16a. Sequence Generation

Participants will be randomly assigned to either control or intervention group with a 1:1 allocation sequence using computer software and will use block randomization with randomly selected block sizes to keep the enrollment sizes in each arm similar throughout the trial. [40] This will be done under the supervision of the study statistician (BP).

16b. Concealment Mechanism

The study team will use a secure web application called Research Electronic Data Capture (REDCap) to randomly allocate participants to the intervention and control arms, which will conceal the sequence and allocation until the point of assignment. [40]

16c. Implementation

All participants who provide consent for participation and who fulfil the inclusion criteria will be randomized. A statistician from the study team will generate the random allocation sequence. Research coordinators of the study will enroll participants and assign them to a study arm (control or intervention arm).

17. Blinding

17a. Blinding (Masking)

Due to the nature of the intervention, neither participants nor researchers will be blinded to the study arm; however, statisticians conducting the outcome analysis will be blinded to which arm participants were assigned. PSWs and other support service staff in the same long-term care and retirement home may be randomized to different study arms, which may cause contamination; however, this is unlikely since those in the control arm will not have access to the navigators.

17b. Emergency Unblinding

Since direct study participants and researchers will not be blinded throughout the duration of the study, unblinding procedures will not be required or necessary for the purposes of this trial

Methods: Data collection, management, and analysis

18. Data Collection Methods

18a. Data Collection Methods

Data will be collected by the Knowledge Translation Program, Li Ka Shing Knowledge Institute, Unity Health Toronto (KTP-UHT). Baseline and exit surveys will be administered online via REDCap.

The study will use the Dillman Total Design Method (follow up at 1, 3, 7, 10 weeks) to increase survey responsiveness. [40] Participants who indicate interest and meet study criteria will be asked to complete a baseline survey at the beginning of the study (0 weeks). If they do not respond immediately, they will receive reminder emails at 1, 3, 7 and 10 weeks. At the 6-month mark, after study completion (26 weeks), participants will be asked to complete an exit survey. If they do not respond immediately, they will also receive reminder emails at 1, 3, 7 and 10 weeks. However, based on whether there are delays in the ability to recruit participants due to a lack of response to recruitment emails and reminders, there is a possibility that the surveys will not take place at the exact times noted above. If this occurs, we will make sure to note this in our limitations. All survey questions have been reviewed by the steering committee for acceptability, clarity of language and feasibility of format (e.g., mobile friendly access).

As mentioned above data will be collected using a baseline and exit survey in addition to an exit interview. Refer to table 1 for a description of the data that will be collected for each data collection method.

Table 1

Data Collection Tool	Objective	Number of participants	Data Collection Time Point	Factors Assessed	Measures used
Baseline Survey	• Outcome evaluation • Demographic information	• up to 154 participants (77 per arm)	• At 0 month, Study Coordinator and Assistant will collect Baseline survey data	• Wellbeing • PROGRESS-Plus factors (gender, sex, religion, education, socioeconomic	• Personal Wellbeing Score (Primary Outcome) • Demographic questionnaire-PROGRESS-Plus

				status, and social capital) • Knowledge • Access to supports • Use of wellness supports	Framework and OHIP number • Maslach Burnout Inventory • Likert scale questions evaluating knowledge, access to and use of wellness supports
Field Notes/Logs	• Process evaluation /Implementation quality	• tracking data for 77 participants	• At 0-6 months, Resource Navigator will collect field notes during intervention	• Implementation quality	• Number of 1:1 resource navigation sessions • Duration of 1:1 resource navigation • Focus of 1:1 resource navigation sessions • adoption (e.g., uptake, utilization, intention to try) of the materials and resources provided
Exit Survey	• Outcome evaluation • Demographic information	• up to 154 participants (77 per arm)	• At 6 months, Study coordinator and Assistant will collect Exit Survey data after completion of intervention	• Wellbeing • PROGRESS-Plus factors (gender, sex, religion, education, socioeconomic status, and social capital) • Knowledge • Access to supports • Use of wellness supports • Satisfaction with the intervention	• Personal Wellbeing Score (Primary Outcome) • Demographic questionnaire-PROGRESS-Plus Framework and OHIP number (if not collected at baseline) • Maslach Burnout Inventory • Likert scale questions evaluating knowledge, access to and use

					of wellness supports
Exit Interview	• Outcome evaluation • Process evaluation /Implement ation quality	• 8-10 participants from intervention arm • 8-10 participants from control arm	• At 6-7 months, Research coordinator will collect interview feedback post intervention	• Barriers and facilitators • Wellbeing • Participant experiences • Suggestions for improvement • Planning for sustainability • Implementation quality	• Interview questions
ICES provincial administr ative database	• Outcome evaluation	• up to 154 participants (77 per arm) (data linkage using OHIP#)	• At 6-7 months, Study coordinator and Assistant will use OHIP number to link administrative data	• Vaccine status • Rates of SARS-CoV-2 infection • Hospitalization • Death	• ICES provincial administrative database fields

18b. Retention

Once a participant is enrolled and randomized into the study, the team will make a concerted effort to ensure participants are followed throughout the study. Since the study has a short intervention period (6 month) that will be adapted to align current work practices, we anticipate that withdrawal will be minimal. To meet our proposed sample size, we included a buffer for participation attrition of 20%, requiring a total of 154 participants (77 per arm). To address retention of participants in completing data measures, the study will provide an incentive to complete the study surveys, all participants will receive a $20 gift card upon each survey completion. The study will use the Dillman Total Design Method (follow up at 1, 3, 7, 10 weeks) to increase survey responsiveness.

19. Data Management

Participant data will be de-identified using a participant I.D. and stored on St Michael's Hospital-Unity Health Toronto's secure server. Identifiers and unique study IDs will be recorded on a master linking log. All study information will be stored according to the process described above until 7 years after the end of the study, after which it will be securely destroyed. Only the study team will have access to the identifying personal information collected for this study.

Baseline and exit surveys will be submitted electronically via REDCap. The survey results will be stored on REDCap until downloaded onto our secure encrypted servers at St. Michael's Hospital- Unity Health Toronto for analysis. We will analyze the quantitative responses using descriptive statistics, and the qualitative data using content analysis.

The interviews will be audio recorded and transcribed verbatim by a member of the study team or NVivo transcription, an automated transcription service. We may use a rapid framework analysis approach to analysis the interview data [41- 45]. Transcripts from the interviews will be double coded in NVivo 11 by two researchers who will independently read transcripts to gain familiarity with the content, conduct open coding and develop a codebook to guide the remainder of the analysis. We will use an intersectional qualitative approach to assess participants' perceptions of wellness and access to resources during the pandemic. [46, 47] (nb: these intersectionality-analysis approaches are nascent, and we will use this study to further contribute to the methodological body of literature). The codebook will be iteratively refined on an ongoing basis and previously coded data will be modified accordingly. The two researchers will double-code 20% of randomly selected transcripts. Inter-rater reliability will be determined by calculating kappa statistics. Coding discrepancies between -1 and 0.6 will be discussed and resolved via a consensus meeting with a third reviewer. Researchers with continue to double-code sets of three transcripts until an interrater reliability of 0.60 or higher is achieved. The remaining transcripts will be single-coded by one of the two researchers who were involved in the consensus meeting.

We will conduct 1-hour semi-structured exit interviews via phone, virtual platform or in-person. During these semi-structured interviews, we aim to ask questions to capture the participants' description of their various identities and relationships among the identities; encourage conversations about the interactions between their identities and social institutions (e.g., work place, social relationships, and community); explore participants' descriptions about their perception of wellness associated with these identities and social institutions; and discuss the narratives about their identities and capacity to access wellness resources during the pandemic [46]. All Interview participants will receive $50 gift card after completion of the interview

20. Statistical Methods

20a. Outcomes

We will use descriptive statistics to report participant demographics and study outcomes. We will use t-tests to compare outcomes for the intervention and control groups. We will disaggregate data by sex, gender, age, long-term and retirement home staff type, and long-term care home type (e.g., for-profit, municipally owned). Where possible (for cells with n≥5), we will disaggregate data by other PROGRESS-Plus demographics, in line with an intersectionality-based approach. [31, 37, 44-45, 48].

20b. Additional Analysis

There is no additional analysis that has been identified for this research study.

20c. Analysis Population and Missing Data

The analysis of the population, as earlier identified, includes a t-test for the comparison of both the control and intervention groups, and also qualitative analysis with the use of NVivo. All questions are optional and participants can skip questions they do not feel comfortable answering. We will consult with a study statistician to develop a plan for missing data.

Methods: Monitoring

21. Data Monitoring

21a. Formal Committee & (b) Interim Analysis

Due to the length and minimal risks associated with the study, a Data Monitoring Committee and interim analysis will not be required. Data will be monitored throughout the duration of the study by the Research Coordinator and Research Assistant in accordance with the Unity Health Toronto Institutional Review Board guidance and standards. The Research Ethics Board may request to review the study records for monitoring purposes.

22. Harms

Participation in this research study is voluntary and there are no known harms associated with this study. The COVID-19 pandemic is a stressful situation to many; therefore, risks will be mitigated by ensuring participants are aware that they have the option to participate and/or not answer any question during the baseline survey, exit survey, intervention and/or interview if selected to participate. It is possible that the survey or interview questions may lead to an emotional response or stress for participants as they recall their experiences during the pandemic. If this happens, we will recommend participants to seek support through their organization's employee assistant program or if their organization does not have such a program, we will provide a list of free support resources. If participants decide that they no longer want to participate or have their data included as part of the research study, they can let a study team member know and their data can be removed up until the data analysis stage.

23. Auditing

We have not included budget for an independent auditing of this study given the nature of the study but will make all study documents available if the funder requests an audit.

Ethics & Dissemination

24. Research Ethics Approval

We will apply for ethics approval from Unity Health Toronto Institutional Review Board.

25. Protocol Amendments

Any important amendments to the protocol will be communicated to study investigators, Unity Health Toronto Institutional Review Board, and study participants.

26. Consent or Assent

26a. Consent or Assent

All interested potential participants (PSW's and other support workers in long-term care and retirement homes) will receive a link to the pre-screening survey (Appendix C) to determine eligibility. If eligible, participants will receive a pre-screening confirmation email (Appendix D) which will contain the link to the study information sheet and informed consent process (Appendix E). Contact information for members of the study team will also be provided. Participants will be encouraged to reach out with any questions. Participants will be asked to review all the study details and provide consent by selecting one of the two consenting statements at the end of the survey. Participants will then be emailed their unique study ID and the link to the baseline survey. The study team will reach out again at 6 months with a link to complete an exit survey.

Consent at enrollment includes participating in:

- 1:1 sessions with the resource navigator and access to educational resources (if assigned to intervention arm. Access to educational resources only (if assigned to the control arm)
- Participation in the baseline survey and exit survey. Participants will be assigned to either an intervention or control arm and will be invited by email (Appendix F - initial email, G - reminder email) to complete the baseline survey, a demographic questionnaire (Appendix H). The baseline survey will be used to select a diverse participant group (purposive sample). Participants will be given the opportunity to consent and provide their OHIP number for data linkage. An invitation email (Appendix I – initial email, J – reminder email) will also be sent to complete the exit survey (Appendix K) where they will also be given the opportunity to provide their OHIP number for data linkage if not provided during the baseline survey.
- Participants' response to any questionnaire will be kept confidential. Participants will be provided with a unique study ID (Appendix F, I) to complete the baseline and exit survey

(Appendix H, K) so that their responses remain de-identified. Identifiers and unique study IDs will be recorded on a master linking log (Appendix L).

At 6 months, we will select and invite 10 participants from the intervention arm and 10 participants from the control arm to take part in a brief key informant interview (mentioned above as an exit interview). We will purposefully sample participants for diversity in role, race/ethnicity, and age. Participants will coordinate with a research staff member for a date/time that works best and also identify their preferred form of communication (Appendix M). Participants will be provided with a reminder email (Appendix N) 2 business days prior to the interview date/time.

Verbal consent will be obtained prior to the start of the interview by the interviewer using a pre-determined script (Appendix O, P) and participants will be given the opportunity have any questions answered. Verbal consent will be captured and recorded once the audio recorder is turned on. Participants will only be identified by participant IDs in the consent recording. Consent to participate will also be recorded on the master linking log (Appendix L). Participants are free to skip questions and/or withdraw from the study.

As an incentive to complete the study surveys, all participants will receive a $20 gift card upon completion of each survey ($20 gift card per survey x 2 surveys = $40 gift card). Participants that complete the interview will also receive a $50 gift card.

27. Confidentiality

All study-related information will be stored on a secure server. In accordance with all applicable privacy legislation, including the *Personal Health Information Protection Act* (PHIPA) of Ontario, Canada, participant personal information will be kept private and confidential.

Participant data will be de-identified using a participant ID and stored on Unity Health's secure server. Identifiers and unique study IDs will be recorded on a master linking log (Appendix L). All study information will be stored according to the process described above until 7 years after the end of the study, after which it will be securely destroyed.

28. Declaration Of Interests

There are no competing interests or conflicts of interest to declare.

29. Access to Data

All participant who complete the baseline survey, intervention and exit survey will be requested to link their study data to their OHIP number. Only the study team will have access to the identifying personal information collected for this study.

30. Ancillary and Post-Trial Care

Ancillary and post-trial care are not applicable for this study.

31. Dissemination Policy

31a. Trial Results

We will use the CIHR End of Grant (EoG) framework to guide EoG dissemination activities tailored to each end user.[48] We will publish our findings in open-access peer reviewed journals, and alongside OPSWA, will present at relevant national conferences. We will use various active and passive strategies to disseminate the findings to knowledge users, including our >20 collaborators via the CITF-funded study including the OLTCA, FCO, Toronto and Ottawa LHINs, Ministries of Health and of LTC, Public Health Agency of Canada, Public Health Ontario, and Healthcare Excellence Canada.[49] We will report the study results using the relevant reporting guidelines including the Consolidated Standards of Reporting Trials (CONSORT) statement, the Template for Intervention Description and Replication (TIDieR) checklist, and the Sex and Gender Equity in Research (SAGER) guidelines.[29, 50-51]

31b. Authorship

We will use the International Committee of Medical Journal Editors (ICMJE) criteria for authorship and no professional writers will be used.

31c. Reproducible Research

As per the funder's guidelines, the study team will make data available after the study has been submitted. The study protocol will also be registered and available via clinicaltrials.gov.

Appendices

32. Informed consent materials

Timeline

Milestone Tasks	Project Month					
	June-July 2022	Aug-Sep 2022	Oct-Nov 2022	Dec 2022 – Feb 2023	March-April 2023	May – June 2023
Assign participants to intervention arm	X					
Baseline survey	X					
Conduct intervention		X	X	X		
Process evaluation tracking		X	X	X		
Exit survey					X	
Conduct exit interviews					X	
Analyze data					X	X
Write final report						X

Budget

Budget Item	Funds requested YEAR 1							
	FTE	hours	Salary	Benefits	Subtotal	In-Kind	Total	Rate
RESEARCH STAFF (excluding trainees)								
Resource Navigator/Officer (RC I)	2.65	5168	$182,554.13	$41,987	$224,542		$224,542	$35.33
Research Coordinator II (0.5FTE)	0.50	975	$38,025.00	$8,746	$46,771		$46,770	$39.00
Research Assistant I (1.0TE)	1.00	1950	$52,767.00	$12,136	$64,903		$64,903	$27.06
Statistician	0.07	133	$7,559.72	$1,739	$9,298		$9,391	$56.84
Summer students (x2)	0.17	336	$6,232.78	$0	$6,233		$6,233	$18.54
Total personnel							**$351,839**	
MATERIALS, SUPPLIES, and SERVICES								
Expendables			**quantity**	**per unit**	**Subtotal**		**Total**	
Cellphone & data/voice plan (2 phones)			2.00	$1,626.00	$3,252		$3,252	
Jabber line			1.00	$10/m	$120		$120	
Voice recorders			2.00	$75.00	$150		$150	
Printing costs (154 participants x ~$10/package)					$3,100		$3,100	
Services								
REDCap			1.00	$2,000	$2,000		$2,000	
Transcription Services			100	$33.28	$3,328		$3,328	
ICES Services					$35,000		$35,000	
Translation Services					$25,000		$25,000	
Knowledge Translation and IKT (Other)								
Maslach Burnout Inventory Scale					$400		$400	
PSW Partners compensation ($400/partner/yr CIHR; $300/part/yr T)			6.00	$400	$2,100		$2,100	
OPSWA Compensation					$13,750		$13,750	
Participant Survey Reimbursement (154 p x 2 surveys/ each grant)			616	$10	$6,160		$6,160	
Participant Interview Reimbursement			20.00	$50	$1,000		$1,000	
Manuscript Publication			4.00	$3,707	$14,828		$14,828	
End of Grant dissemination materials					$3,500		$3,500	
Total materials					**$113,688**		**$113,688**	
Travel								
Travel & Presentation at National Conferences					$2,400		$2,400	
Total Travel					**$2,400**		**$2,400**	
EQUIPMENT								
Laptops (Dell Latitude 7400)			3.00	$3,500	$10,500		$10,500	
Audio voice recorders			1.00	$75	$75		$75	
Total equipment					**$10,575**		**$10,575**	
TOTAL							**$478,502**	

References

1. Guidance for Clinical Trial Protocols. Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT). https://www.spirit-statement.org/. Updated 2019 Dec 13.

2. Considerations when paying patient partners in research. https://cihr-irsc.gc.ca/e/51466.html. Updated 2021 Sept 15.

3. Hsu AT, Lane NE, Sinha SK, Dunning J, Dhuper M, Kahiel Z, Sveistrup H. Understanding the impact of COVID-19 on residents of Canada's long-term care homes — ongoing challenges and policy responses. International Long-Term Care Policy Network, CPEC-LSE. https://ltccovid.org/wp-content/uploads/2020/06/LTCcovid-country-reports_Canada_June-4-2020.pdf. Published 2020 June 4.

4. Lum JM, Sladek, J, Ying A, Payne LH. Ontario Personal Support Workers in Home and Community Care: CRNCC/PSNO Survey Results. https://www.ryerson.ca/content/dam/crncc/knowledge/infocus/factsheets/InFocus-Ontario%20PSWs%20in%20Home%20and%20Community%20Care.pdf. Published 2010.

5. Ministry of Long-Term Care. Long-Term Care Staffing Study. ON: Long-Term Care Staffing Advisory Group; 2020:1-50.

6. Estabrooks CA, Straus S, Flood, CM, Keefe J, Armstrong P, Donner G, Boscart V, Ducharme F, Silvius J, Wolfson M. Restoring trust: COVID-19 and the future of long-term care. Royal Society of Canada. https://rsc-src.ca/sites/default/files/LTC%20PB%20%2B%20ES_EN.pdf. Published 2020.

7. How Ontario is responding to COVID-19. Government of Ontario. https://www.ontario.ca/page/how-ontario-is-responding-covid-19 Updated 2021. Accessed 2021 Feb 18.

8. Duan Y, Iaconi A, Song Y, et al. Care Aides Working Multiple Jobs: Considerations for Staffing Policies in Long-Term Care Homes During and After the COVID-19 Pandemic. J Am Med Dir Assoc. 2020;21(10):1390-1391. doi:10.1016/j.jamda.2020.07.036

9. Izenberg D, Taylor M. Who are Ontario's personal support workers? Healthy Debate. https://healthydebate.ca/2018/03/topic/psws-ontario/. Published 2018 Mar 1.

10. Oatley B. Personal support workers risk their own health to care for others. Canada's National Observer. https://www.nationalobserver.com/2020/12/18/news/covid-19-risks-more-people-becoming-personal-support-workers. Published 2021 Jan 4.

11. Overworked and undervalued, a crisis for personal support workers. CBC News. https://www.cbc.ca/news/canada/sudbury/personal-support-workers-sudbury-crisis-1.5143707. Published May 22, 2019.

12. CUPE Ontario and the Ontario Council of Hospital Unions. Ontario's Long-Term Care COVID-19 Commission [Internet]. 2021 [cited 2022 Jan 31]. Available from: https://cupe.on.ca/wp-content/uploads/2021/03/Brief_LTC_Commission_Submission_OD_and_OCHU_2021_02_16.pdf

13. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implement Sci. 2011;6:42. Published 2011 Apr 23. doi:10.1186/1748-5908-6-42

14. Rios P, Radhakrishnan A, Williams C, et al. Preventing the transmission of COVID-19 and other coronaviruses in older adults aged 60 years and above living in long-term care: a rapid review. Syst Rev. 2020;9(1):218. Published 2020 Sep 25. doi:10.1186/s13643-020-01486-4

15. Rios P, Radhakrishnan A, Thomas SM, Darvesh N, Straus SE, Tricco AC. Preventing respiratory illness in older adults aged 60 years and above living in long-term care. MedRxiv. 2020; 1-25. https://doi.org/10.1101/2020.03.19.20039081

16. IPAC+ Self-Assessment for Long-term Care Facilities (LTCHs) and Retirement Homes (RHs). https://ipac.knowledgetranslation.ca/. Accessed 2021 Feb 18.

17. IPAC+ Resource Library. Regional Geriatric Program of Toronto. https://www.rgptoronto.ca/resources/ipac+/. Updated 2021.

18. Mental Health and COVID-19. Centre for Addiction and Mental Health (CAMH). https://www.camh.ca/en/health-info/mental-health-and-covid-19/information-for-professionals. Published 2020.

19. Mental Health Supports. Wellness HUB Support for Congregate Living Centres. https://wellness-hub.ca/tag/mental-health-supports/. Published 2021.

20. Wraparound Resources Package. Wellness Hub. https://wellness-hub.ca/res/wraparound-resources-package/. Published 2021.

21. Caregiver Resources. The Ontario Caregiver Organization. https://ontariocaregiver.ca/resources-education/caregiver-resources/#caring-for-yourself. Published 2021.

22. What you need to know about getting the COVID-19 vaccine. Wellness Hub. https://wellness-hub.ca/res/what-you-need-to-know-about-getting-the-covid-19-vaccine/. Published 2021.

23. February 2nd, 2021 OPSWA Town Hall #2: COVID vaccine questions answered. Knowledge Translation Program. https://www.youtube.com/watch?v=UCzRgtbHFFQ&t=517s. Published 2021 Mar 31.

24. March 23rd, 2021 OPSWA Town Hall #3: Get you COVID vaccine questions answered. Knowledge Translation Program. https://www.youtube.com/watch?v=hNrNsTXKGT8&t=3s. Published 2021 Mar 26.

25. Knowledge Translation Program. COVID-19 Knowledge Translation. https://knowledgetranslation.net/expertise/covid-19/. Updated 2021.

26. COVID-19 Immunity Task Force. Pan-Canadian studies investigate why COVID-19 has been devastating to long-term care facility residents and staff.

27. Ministry of Long-Term Care. Long-term care overview. https://www.ontario.ca/page/about-long-term-care

28. Ontario Retirement Communities Association. Retirement Living. https://www.orcaretirement.com/retirement-living-faqs/#1497033882095-700b1121-ba88

29. Ontario Long Term Care Association. https://www.oltca.com/oltca/OLTCA/Public/LongTermCare/FactsFigures.aspx

30. The Wellness Hub Study. https://wellness-hub.ca/research/study-information/

31. Benson T, Sladen J, Liles A, et al. Personal Wellbeing Score (PWS)—a short version of ONS4: development and validation in social prescribing. BMJ Open Quality. 2019;8:e000394. doi:10.1136/ bmjoq-2018-000394. Accessed 2021 Feb 19.

32. World Health Organization. https://www.who.int/healthpromotion/about/HPR%20Glossary_New%20Terms.pdf

33. Maslach C, Jackson SE. Maslach Burnout Inventory - Human Services Survey for Medical Personnel. Mind Garden. https://www.mindgarden.com/315-mbi-human-services-survey-medical-personnel. Accessed 2021 Feb 19.

34. Maslach C, Jackson SE, Leiter M. The Maslach Burnout Inventory Manual. https://www.researchgate.net/publication/277816643. Published 1997. Accessed 2021 Feb 19. 64.

35. Poghosyan L, Aiken LH, Sloane DM. Factor structure of the Maslach burnout inventory: an analysis of data from large scale cross-sectional surveys of nurses from eight countries [published correction appears in Int J Nurs Stud. 2014 Oct;51(10):1416-7]. Int J Nurs Stud. 2009;46(7):894-902. doi:10.1016/j.ijnurstu.2009.03.004

36. Koeske GF, Koeske RD. Construct Validity of the Maslach Burnout Inventory: A Critical Review and Reconceptualization. J Appl Behav Sci. 1989;25(2):131–44. http://journals.sagepub.com/doi/10.1177/0021886389252004. Accessed 2021 Feb 19.

37. O'Neill J, Tabish H, Welch V, et al. Applying an equity lens to interventions: using PROGRESS ensures consideration of socially stratifying factors to illuminate inequities in health. *J Clin Epidemiol*. 2014;67(1):56-64. doi:10.1016/j.jclinepi.2013.08.005. Accessed 2021 Feb 19

38. ICES Data. Institute for Clinical Evaluative Sciences (ICES). https://www.ices.on.ca/Data-and-Privacy/ICES-data. Updated 2021.

39. ICES COVID-19 Dashboard. Institute for Clinical Evaluative Sciences (ICES). https://www.ices.on.ca/DAS/AHRQ/COVID-19-Dashboard. Updated 2021

40. How REDCap is being used in response to COVID-19. Research Electronic Data Capture (REDCap). https://www.project-redcap.org/. Accessed 2021 Feb 19.

41. Hoddinott SN, Bass MJ. The Dillman Total Design Survey Method. Can Fam Physician. 1986;32:2366-8

42. Taylor B, Henshall C, Kenyon S, Litchfield I, Greenfield S. (2018). Can rapid approaches to qualitative analysis deliver timely, valid findings to clinical leaders? A mixed methods study comparing rapid and thematic analysis. BMJ Open. 8(e019993): 1-13.

43. Johnson GA, Vindrola-Padros C. (2017). Rapid qualitative research methods during complex health emergencies: A systematic review of the literature. Soc Sci Med. 189: 63-75.

44. Hankivsky O, Grace D. Understanding and emphasizing difference and intersectionality in multimethod and mixed methods research. In: Hesse-Biber SN, Johnson RB, eds. The Oxford Handbook of Multimethod and Mixed Methods Research Inquiry. Oxford University Press; 2015.

45. Bauer GR. Incorporating intersectionality theory into population health research methodology: Challenges and the potential to advance health equity. Soc Sci Med. 2014;110:10-17. https://doi.org/10.1016/j.socscimed.2014.03.022

46. Narvaez RF, Meyer IH, Kertzner RM, Ouellette SC, Gordon AR. A Qualitative Approach to the Intersection of Sexual, Ethnic, and Gender Identities. Identity (Mahwah, N J). 2009;9(1):63-86. doi:10.1080/15283480802579375

47. Eslava-Schmalbach J, Garzon-Orjuela N, Elias V, et al. Conceptual framework of equity-focused implementation research for health programs (EquIR). Int J Equity Health. 2019;18(1):80. doi: 10.1186/s12939-019-0984-4. Accessed 2021 Apr 13.

48. Bauer GR, Braimoh J, Scheim AI, Dharma C. Transgender-inclusive measures of sex/gender for population surveys: Mixed-methods evaluation and recommendations. PLoS One. 2017;12(5):e0178043. doi:10.1371/journal.pone.0178043

49. Guide to Knowledge Translation Planning at CIHR: Integrated and End-of-Grant Approaches 2015A. Available from: https://cihr-irsc.gc.ca/e/45321.html#a7

50. Our partners. Knowledge Translation Program. Wellness Hub. https://wellness-hub.ca/. Updated 2021.

51. CONSORT Group. CONSORT - Transparent Reporting of Trials [Internet]. Consort-statement.org. 2010. Available from: http://www.consort-statement.org/

52. UK EQUATOR Centre. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide | The EQUATOR Network [Internet]. www.equator-network.org. 2022. Available from: https://www.equator-network.org/reporting-guidelines/tidier/