INTRODUCTION

The aim of this study was to evaluate the effectiveness of adding a blended web-based and in-person training program in interprofessional SDM for home care teams to passive dissemination of a decision guide on the proportion of frail elders or caregivers reporting an active role in making housing decisions, compared with passive dissemination of the decision guide.

Does your paper address CONSORT subsection 2b? Yes. "We hypothesized that the addition of a training program in IP-SDM to the passive dissemination of a decision guide would increase the proportion of frail elders or caregivers reporting an active role in the decision-making process."
Yes, "The web-based tutorial ensured that all participants arrived at the workshop with a similar knowledge of SDM concepts. The workshop included a lecture reviewing SDM concepts (especially the interprofessional SDM approach); a video demonstrating the approach in a home care team with a frail elder making a housing decision[20]; training in using the decision guide[4]; and role play using the decision guide with feedback from facilitators[15, 20]. The workshop, based on[21] included decision-making about housing decisions with frail elders, communication techniques and, for frail elders with cognitive impairment, strategies for managing their participation or that of their caregivers in decision-making. Workshops were held in health care teams of health centers in Quebec, Canada".

5-i) Describe the history/development process

Yes, and we provided a reference for more details."The intervention consisted of (1) a 1.5 hour web-based tutorial, based on the Ottawa Decision Support Tutorial[19] completed by home care teams at the cluster level; followed by (2) a 3.5 hour live interactive workshop. The web-based tutorial ensured that all participants arrived at the workshop with a similar knowledge of SDM concepts.*

5-ii) Describe the intervention

Yes, "The primary outcome of our intervention is available online on a site whose references we have provided to ensure reproducibility. It was accessible by registration on the site[18] and has the potential to help health professionals discuss with frail elders of cognitively-impaired frail elders the decision about the location of care[4, 9, 13].* [18] described the website.

5-iii) Report any prompts/reminders used

Not applicable. There is no intended 'doses' and optimal timing for use.

5-xi) Report any prompts/reminders used

We did not use a specific recall and this is one of the limitations of our study. "Periodic reminders[61] and post-intervention coaching could have increased long-term effects and fidelity."[62] Changing clinical, organizational and policy-making environments can have major impacts on pragmatic trials such as ours."

5-xii) Describe any co-interventions (incl. training/support)

Not applicable. The intervention at various time points. The decision guide distributed before the intervention was still available in sufficient quantities afterwards.[15] The decision guide, adapted from the online family decision support tool to the context of the home was developed in French and English versions[4, 18, 18*][18]. https://decisionaids.ohri.ca/ODST/

6a-i) Describe whether, how, and when qualitative feedback from participants was obtained

Not applicable. In the study we did not have any co-intervention to describe.

6a) CONSORT: Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed

Yes, "The primary outcome was the frail elders' or caregivers' perception of the role they assumed in decision-making as measured using a modified version of the Control Preferences Scale,[27] a single question with five response categories: (A) I made the decision, (B) I made the decision after seriously considering the healthcare professionals' opinions, (C) the healthcare professionals and I shared the responsibility for the decision making, (D) the healthcare professionals made the decision after seriously considering my opinion, and (E) the healthcare professionals made the decision. For sample size calculation and analysis, we dichotomized the primary outcome by collapsing categories A, B and C into 'active role' and D and E into 'passive role' in decision-making.

Secondary outcomes assessed in frail elders and caregivers were (1) their preferred option about whether the cognitively older adult should stay at home or move to another location, and the actual decision made; (2) decision conflict, assessed with the 16-item Decisional Conflict Scale[28, 29]; (3) decision regret, assessed with the 5-item Decision Regret Scale[30]; and (4) perception of the extent to which health professionals involved them in decision-making, assessed with the D-OPTION scale, a 12-item instrument evaluating SDM behaviors during decision-making.[31, 32] Secondary outcomes for frail elders alone was health-related quality of life, assessed with the 36- items of the Nottingham Health Profile.[33-35] and for caregivers alone, burden of care, assessed with the Zarit Burden Inventory scale[36-38]. Yes, the web component of our intervention is available online on a site whose references we have provided to ensure reproducibility. "It was accessible by registration on the site[18] and has the potential to help health professionals discuss with frail elders of cognitively-impaired frail elders the decision about the location of care[4, 9, 13]. * [18] described the website."

6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained

Not applicable. No online questionnaire was used in the study.

6a-iv) Describe whether, how, and when qualitative feedback from participants was obtained

Not applicable. In the study we did not have any co-intervention to describe.

6a-v) Description of the intervention

Yes. "Dissemination of the decision guide was passive in the sense that although distributed in the health centers, we did not train the teams in how to use it. The decision guide, adapted from the online family decision support tool to the context of the home was developed in French and English versions[4, 18, 18*][18]. https://decisionaids.ohri.ca/ODST/"

6a-vi) Description of the intervention

5-xi) Report any prompts/reminders used

No revision or update was made. We had one intervention and one comparator

6a-vii) Description of the intervention

5-viii) Mode of delivery, features/functionality/components of the intervention and comparator, and the theoretical framework

Yes. "The primary outcome was the frail elders' or caregivers' perception of the role they assumed in decision-making as measured using a modified version of the Control Preferences Scale,[27] a single question with five response categories: (A) I made the decision, (B) I made the decision after seriously considering the healthcare professionals' opinions, (C) the healthcare professionals and I shared the responsibility for the decision making, (D) the healthcare professionals made the decision after seriously considering my opinion, and (E) the healthcare professionals made the decision. For sample size calculation and analysis, we dichotomized the primary outcome by collapsing categories A, B and C into 'active role' and D and E into 'passive role' in decision-making.

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6a-ix) Describe use parameters

No revision or update was made. We had one intervention and one comparator

6a-x) Clarify the level of human involvement

Not applicable. There is no intended 'doses' and optimal timing for use.

6a-xi) Clarify the level of human involvement

Not applicable. For the online tutorial, no dose was relevant the health professional have to complete the tutorial.

6a-xii) Describe whether, how, and when qualitative feedback from participants was obtained

Yes, "However, our intervention overcomes the disadvantages of web-based learning (mainly isolation)[23-25], by the in-person part of the training, which provided role play, feedback and discussion opportunities for applying knowledge to skills and behavior.[28]"

6b) CONSORT: Any changes to trial outcomes after the trial commenced, with reasons

Yes. "We conducted a cross-sectional stepped-wedge cluster randomized trial (the IPSDM-SW Study) from November 2014 to December 2018 with the home care teams of health centers in Quebec, Canada."

7a) CONSORT: How sample size was determined

Yes. "The sample size calculation was informed by preliminary data from another stepped-wedge designs[43]. We assumed an average of eight frail elders and eight caregivers per health center in each data collection period and a time-invariant intra-class correlation (ICC) of 0.05.[44] To detect an absolute increase of 20%[45] in the primary outcome (from 70% to 90%) with 80% power using a stepped-wedge design with four clusters and a two-sided test at the 5% significance level, a total of eight clusters (with a total of 320 caregivers) was required,[46] meaning 320 frail elders and 320 caregivers of frail elders with cognitive impairment. To prevent any loss to follow-up of clusters, we recruited one more health center than planned."

7b) CONSORT: When applicable, explain any interim analyses and stopping rules

Yes. "The primary outcome was the frail elders' or caregivers' perception of the role they assumed in decision-making as measured using a modified version of the Control Preferences Scale,[27] a single question with five response categories: (A) I made the decision, (B) I made the decision after seriously considering the healthcare professionals' opinions, (C) the healthcare professionals and I shared the responsibility for the decision making, (D) the healthcare professionals made the decision after seriously considering my opinion, and (E) the healthcare professionals made the decision. For sample size calculation and analysis, we dichotomized the primary outcome by collapsing categories A, B and C into 'active role' and D and E into 'passive role' in decision-making.

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8a) CONSORT: Method used to generate the random allocation sequence
Yes. "Health centers (clusters) were randomized to one of four sequences. Once participating home care teams had been identified, an independent biostatistician at the Ottawa Hospital Research Institute’s Methods Centre performed randomization using computer-generated numbers. Given the nature of the intervention, the investigators, project coordinator and research assistants (RAs) collecting the data were not blinded. However, the allocation list was concealed from the research team for as long as possible and RAs were asked not to discuss this information with any frail elder or caregiver and not to refer to the intervention. Frail elders and caregivers were blinded to the intervention."

8b) CONSORT: Type of randomisation; details of any restriction (such as blocking and block size)
Yes. Health centers (clusters) were randomized to one of four sequences. Once participating home care teams had been identified, an independent biostatistician at the Ottawa Hospital Research Institute’s Methods Centre performed randomization using computer-generated numbers. Given the nature of the intervention, the investigators, project coordinator and research assistants (RAs) collecting the data were not blinded. However, the allocation list was concealed from the research team for as long as possible and RAs were asked not to discuss this information with any frail elder or caregiver and not to refer to the intervention. Frail elders and caregivers were blinded to the intervention.

9) CONSORT: Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned
Yes. “an independent biostatistician at the Ottawa Hospital Research Institute’s Methods Centre performed randomization using computer-generated numbers.”

10) CONSORT: Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
Yes. "an independent biostatistician at the Ottawa Hospital Research Institute’s Methods Centre performed randomization using computer-generated numbers."

11a) CONSORT: Blinding - if done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
Yes. "Participants when applicable were only aware of the intervention but they did know what was the comparator. "Home care teams made lists of potentially eligible frail old patients. Trained RAs assigned to each health center contacted these patients or caregivers of frail elders with cognitive impairment and asked if they would participate. Then RAs met all interested participants at their home or a place of their choice to complete informed consent and proceed with data collection. Data collection took place from November 2015 to December 2018. Due to practical constraints, some health centers started the intervention earlier or later than planned. Self-reported data collected were outcomes, relationship between caregivers and frail elders (when appropriate) and sociodemographic characteristics including age, sex, and education, variables included in our primary outcome: younger, female, and well-educated people (secondary school level or higher) are more likely to take an active role in decisions about their health [27, 39- 41]."

11b) CONSORT: If relevant, description of the similarity of interventions
Not relevant for the study.

12a) CONSORT: Statistical methods used to compare groups for primary and secondary outcomes
Yes. "The primary outcome was analyzed using a generalized linear mixed model (GLMM) with logit link. The pre-specified primary analysis assumed a uniform within- and between-period correlation, adjusting for time effects (categorical) and specifying a random effect for cluster." [43]

12a-i) Imputation techniques to deal with attrition / missing values
Yes. Missing rate was very low (less than 5%) and we did not use imputation method. "Missing data rate is 98%.”

12b) CONSORT: Methods for additional analyses, such as subgroup analyses and adjusted analyses
Yes. "We performed secondary analyses by additionally adjusting for primary outcome predictors and for imbalanced baseline characteristics [47, 48]." To explore the implications of bias due to misspecification of the correlation structure, we conducted analyses using two other correlation structures identified in the literature: nested exchangeable (specifying a random cluster effect) and exponential."

13a) CONSORT: For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome
Yes. "Of 481 frail elders contacted, 311 (64.6%) were recruited. Of 502 eligible caregivers contacted, 339 (67.5%) were recruited."

13b) CONSORT: For each group, losses and exclusions after randomisation, together with reasons
Yes. "There was no loss to follow-up of health centers and no frail elders, caregivers or health centers were excluded."

13c) CONSORT: Attrition diagram
Yes. "Figure 1. Flowchart for the trial by allocated sequence and period"

14a) CONSORT: Dates defining the periods of recruitment and follow-up
Yes. "Recruitment took place from November 2014 to December 2018. Interprofessional home care teams from nine health centers with 281 health professionals participated in the study."

14a-i) Indicate if critical “secular events” fell into the study period
No change in the the internet resources fell into the study period.

14b) CONSORT: Why the trial ended or was stopped (early)
The stepped wedge cluster randomized trial was completed.

15) CONSORT: A table showing baseline demographic and clinical characteristics for each group
Yes. "Table 2: Baseline characteristics of participants"

15i) Report demographics associated with digital divide issues
Yes. "Participating frail elders were on average 81.2 (SD: 7.5) years old; 66.9% were female and 58.8% had secondary education or higher. Baseline characteristics were well-balanced between intervention and control except for education level (Table 1). Caregivers of frail elders with cognitive impairment were on average 66.4 years old (SD: 11.7); 70.5% were female and 87.3% had secondary education. Most caregivers (72%) were retired or at home and 90.3% were the child, spouse, or husband of the frail elder. Among caregivers, baseline characteristics were well-balanced between intervention and control, except for age (Table 2)."

16a) CONSORT: For each group, number of participants (denominator) included in each analysis and whether the analysis was by assigned groups
Yes. "Health centers (clusters) were randomized to one of four sequences. Once participating home care teams had been identified, an independent biostatistician at the Ottawa Hospital Research Institute’s Methods Centre performed randomization using computer-generated numbers."
We did not perform qualitative analysis itself. "However, our intervention overcame the disadvantages of web-based learning (mainly isolation) [23-25], by the in-person part of the training, which provided role play, feedback and discussion opportunities for applying knowledge to skills and behavior[26]. No change in the outcomes was observed."

### DISCUSSION

#### CONSORT: Trial limitations, addressing sources of potential bias, imprecision, multiplicity of analyses

- **20) CONSORT: Typical limitations in ehealth trials**
  - Yes, "Limitations section in the Discussion"

#### CONSORT: Generalisability (external validity, applicability) of the trial findings

- **21-i) Generalizability to other populations**
  - Yes, "At the individual level, however, results of this study are generalizable to frail elders and caregivers of frail elders with cognitive impairment with similar characteristics facing housing decisions."

#### CONSORT: Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

- **22) CONSORT: Discuss if there were elements in the RCT that would be different in a routine application setting**
  - Yes, "Pragmatic trials are more applicable to real clinical practice[65] and increase external validity"

#### CONSORT: Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)

- **22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)**
  - Yes, "We observed a non-significant on the outcomes."

#### CONSORT: Generalisability to other populations

- **21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting**
  - Yes, "We designed a pragmatic trial" Pragmatic trials are more applicable to real clinical practice[65] and increase external validity"

#### CONSORT: Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

- **22-ii) Highlight unanswered new questions, suggest future research**
  - Yes, "It may be possible that there is a lack of fidelity of implementation of the intervention. In this pragmatic trial we were not able to be present in the consultations to assess this, but a future mixed-methods or qualitative study could provide this information and help us to better see the impact of the intervention"

### Other information

#### CONSORT: Registration number and name of trial registry

- "The trial was registered (NCT02592525)"

#### CONSORT: Where the full trial protocol can be accessed, if available

- "Yes, "the protocol was published."

#### CONSORT: Sources of funding and other support (such as supply of drugs), role of funders

- **Defined in the protocol: [15]**

#### Comment on ethics committee approval

- Yes, "Ethics committee review approval has been obtained from the Multicenter Ethics Committee of CISSS-Laval."

#### Outline informed consent procedures

- Yes, informed consent was obtained offline. "Home care teams were eligible if they: (1) were involved in caring for frail elders; (2) practiced in one of the health centers participating in the trial; and (3) were interprofessional, i.e., involved more than two health professionals from different professions, (4) provided informed consent to participate in the study. Frail elders were eligible if they: (1) were aged ≥65; (2) were receiving care from the home care teams; (3) had made a decision about staying home or moving during the recruitment periods; (4) were able to read, understand and write French or English; (5) were able to give informed consent. When frail elders were cognitively-impaired, their informal caregiver became the eligible participant. Caregivers were defined in this study as close relatives or friends and were eligible if they: (1) were caring for a cognitively-impaired elder who was otherwise eligible; (2) were able to read, understand, and write French or English; and (3) provided informed consent to participate in the study. Frail elders with cognitive impairment had been clinically evaluated by a health professional as no longer able to make decisions on their own."

#### Safety and security procedures

- Procedures were completely secure. "Home care teams made lists of potentially eligible frail older patients. Trained RAs assigned to each health center contacted these patients or caregivers of frail elders with cognitive impairment and asked if they would participate. Then RAs met all interested participants at their home or a place of their choice to complete informed consent and proceed with data collection. Data collection took place from November 2015 to December 2018. Due to practical constraints, some health centers started the intervention earlier or later than planned. Self-reported data collected were outcomes, relationship between caregivers and frail elders (when appropriate) and sociodemographic characteristics including age, sex, and education, variables identified as predictors of our primary outcome: younger, female, and well-educated people (secondary school level or higher) are more likely to take an active role in decisions about their health[27, 39-41]."

#### State the relation of the study team towards the system being evaluated

- Yes, "None declared conflict of interest"