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Integration of Sex and Gender in a Continuing Professional Development Course on Diabetes and Depression: A Mixed Methods Feasibility study

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Abstract

Objectives Assess the feasibility and impact of a continuous professional development (CPD) course on type-2 diabetes and depression on health professionals' intention to include sex and gender considerations in patient care.

Design and setting In collaboration with CPD organisations and patient-partners, we conducted a mixed-methods feasibility controlled trial with post-intervention measures in three Canadian provinces.

Participants Of 178 eligible health professionals, 127 completed questionnaires and 67 participated in semi-structured group discussions.

Intervention and comparator An interactive one-hour CPD course, co-designed with patient-partners, on diabetes and depression with sex and gender considerations (intervention) was compared to a similar course without these considerations (comparator).

Outcomes Feasibility of recruitment and retention of CPD organisations and patient-partners throughout the study; adherence to planned activities; health professionals' intention to include sex and gender considerations in patient care as measured by the CPD-Reaction questionnaire; and barriers and facilitators using the Theoretical Domains Framework.

Results All recruited CPD organisations and patient-partners remained engaged throughout the study. All planned CPD courses occurred. Overall, 71% of eligible health professionals participated (63% under 44 years old; 79.5% female; 67.7% practising in French; 66.9% practising in Quebec; 78.8% in urban practice). After training, mean intention scores for the intervention (n=49) and control groups (n=78) were 5.65 ± 0.19 and 5.19 ± 0.15, respectively. Mean difference was -0.47 (CI -0.95 to 0.01; p=0.06). Adjusted for age, sex and practice settings, mean difference was -0.57 (CI -1.09 to 0.05; p=0.03). We identified eight Theoretical Domains related to barriers and six related to facilitators for providing sex- and gender-adapted diabetes and depression care.

Conclusions CPD training on diabetes and depression that includes sex and gender considerations is feasible and, compared to CPD training that does not, may prompt health

professionals to modify their care. Addressing identified barriers and facilitators could increase intention.

Registration number: NCT03928132 with ClinicalTrials.gov.

Keywords: Sex and gender, knowledge translation, continuous professional development, diabetes, depression, patient engagement, Theory of Planned Behaviour, Theoretical Domains, COM-B

Strengths and limitations of this study

- Continuous professional development (CPD) courses that included sex and gender considerations were co-designed with patients experiencing diabetes and/or depression.
- Outcome measures were informed by theory.
- This mixed-methods controlled trial used post-intervention measures only as pre-intervention measures were not feasible. Although randomized allocation of participants was not possible, it was feasible to conduct a mixed-methods controlled trial.

INTRODUCTION

A variety of research initiatives are attempting to reduce health inequities between men and women (1, 2). Research that includes sex- and gender-based analysis results in more accurate evidence, more relevant recommendations, more specifically-targeted interventions, and better outcomes (3-6). Sex differences are biology-linked differences between females and males caused by different sex chromosomes, sex-specific gene expression of autosomes, sex hormones, and their effects on organ systems (7). Gender differences arise from sociocultural processes such as the different behaviours of women and men, their exposure to environmental influences, impacts of nutrition, lifestyles or stress, and attitudes towards illness, treatment and prevention (7). Gender roles and gender identity are influenced by a complex interplay between genetic, endocrine, and social factors (8). Finally, sex or gender are not straightforward binary categories. Many femininities and masculinities exist and can influence other important sociodemographic variables (9).

Disease manifestation and outcomes differ between men and women. For example, twice as many women suffer from depression, and three times as many men commit suicide (5, 10, 11). Recent evidence supports a link between type 2 diabetes (T2D) and depression, and findings suggest that there are differences between men and women at the levels of predisposition, risk factors, clinical representation, disease outcome, comorbidity and treatment efficacy (7, 9). Gender described by psychosocial influences, rather than biological differences, can also affect individuals with T2D and depression (7, 12, 13). For example, women are at greater risk of suffering from insomnia and sleep deprivation, which are both correlated with obesity and depression (7, 14).

These findings have yet to be translated adequately into clinical practice (2). For example, a 2017 review suggested that only 35% of studies on Canadian practice guidelines, a cornerstone of knowledge translation, reported screening, diagnosis or management considerations specific to sex or gender, and only 25% used the terms “sex” and “gender” correctly (15).

Professional development (CPD) is another cornerstone of knowledge translation as it mobilizes professional and regulatory bodies as well as educational institutions to foster

changes in clinical practice (16, 17). We define CPD as all educational activities serving to maintain or increase the knowledge, skills, work performance, and relationships that a clinician needs to serve patients, the public or the profession (5, 18, 19). We argue that integrating sex and gender considerations in CPD, one of the most effective strategies for changing clinical practice, will help address the inequities between men and women. We aimed to assess the feasibility and impact of including sex and gender considerations in a CPD course on T2D and depression on health professionals' intention to include sex and gender considerations in patient care.

METHODS

Study design and setting

We conducted a non-randomized mixed-methods study with a concurrent embedded design: (1) a two-arm non-randomized controlled trial with post-intervention measures only; and (2) semi-structured group discussions following the CPD course. We used the Theory of Planned Behavior for quantitative analysis, Theoretical Domains Framework (TDF) for qualitative analysis, and the COM-B model to triangulate findings. We followed the CONSORT extension for Pilot and Feasibility Trials Checklist to report results (20).

This project is one of six that were funded by the Canadian Institutes of Health Research to explore sex and gender issues in knowledge translation (21), gender transformative approaches to knowledge translation, and sex- and gender-based analysis (5, 21).

A multidisciplinary team was created of 25 researchers: two sex and gender specialists, three patient-partners with experience with T2D and/or mental health issues (two males and one female), two physicians, one nurse, two CPD managers, one research assistant and two trainees. An executive committee of 12 team members (including all patient-partners) held monthly meetings addressing the main concerns in each research phase. They chose the clinical topic of the course based on needs expressed by CPD providers on the team. They then adapted an existing diabetes and depression CPD course to include sex and gender considerations and contacted CPD providers in three Canadian provinces to collaborate on implementing the courses.

Patient involvement

Three patient-partners, core members of the executive committee, contributed to governance (e.g., attending meetings and courses, making executive decisions) and intervention design. They contributed their experience to the CPD course, helped collect data and interpret results, coauthored this paper and advised us on plain language use for our presentations.

Participants and recruitment

All health professionals working in the clinical settings where our CPD course was advertised, including hospitals and family medicine groups, or participating in the continuing medical education (CME) conference where the course was to be offered, were invited to participate. Our key CPD partners were physicians but we invited all health professionals to the courses. Eligible participants were invited by email and through the Internet registration platforms of CME conferences in three Canadian provinces (Quebec, Ontario, New-Brunswick). Participants stayed in their respective groups for the semi-structured group discussion that immediately followed the CPD course. Inclusion criteria were: practising health professionals available to participate in person for the whole course; and fluent in French (all our CPD courses were in French). Ethical approval was obtained from the Centre intégré universitaire de santé et de services sociaux de la Capitale-Nationale (CIUSSS-CN) Ethics Board (2017-2018-16 MP), the Hôpital Montfort Research ethics board (19-20-05-009), and the Vitalité Health Network research ethics board (CER-2019-18).

Intervention

Informed by a needs assessment of physicians by our key CPD stakeholder, Médecins Francophone Canada, we chose patients with T2D and depression combined as the clinical topic. There is growing evidence of a link between T2D and depression and the influence of sex and gender in patients with this comorbidity (22, 23). The team adapted an existing T2D and depression CPD course to include evidence-based sex and gender considerations. The original course, a 1-hour classroom-based activity, describes links between TD2 and depression, reviews CANMAT 2016 Depression Guidelines and

reviews pharmacological and non-pharmacological treatment of TD2 and depression. We added sex- and gender-specific content including: 1) definitions and differences between the concepts of sex and gender, 2) epidemiological data on the differences in incidence, prevalence, morbidity and mortality between men and women with T2D and depression, and 3) a video explaining sex biases associated with these two conditions. The adapted CPD course (intervention) kept the original duration (one hour) and medical content of the original course (comparator). Links between DT2 and depression were explained together with sex and gender differences and reviews of pharmacological and non-pharmacological treatments were condensed. As per patient-partners' recommendations, we also held 30-minute semi-structured group discussions with both the intervention and control group immediately following the course. In the group discussion we presented a clinical case vignette on managing a patient with T2D and depression in which the health professional's behaviour exhibited various inconsistencies with best clinical practices. We asked participants to write down the main inconsistency and to categorize it within five categories determined by our team:1) failure to mention positive factors for recovery, 2) failure to engage the patient in their health-related decision, 3) sex and gender biases, 4) failure to take into account notions of sex and gender, and 5) cannot be categorized. We prompted participants to discuss their perception of sex and gender considerations by linking them to the clinical vignette and to their clinical experience of integrating sex and gender considerations in general.

Depending on the setting (hospitals, family medicine groups, CME conferences) we either (1) assigned the participants to the control or intervention group on their arrival to achieve a balanced number of participants in both groups or (2) the participants registered in one group or the other, both groups being blinded to the intervention and control group. Efforts were made to equally divide groups regarding number and sex of participants. At registration, participants were told that it was a research project that required their consent. Participants could attend the course and receive CME credits whether they chose to participate in the study or not. All CPD courses were delivered by the same two physicians (one male, assigned to the control group, and one female, assigned to the intervention group) in all the research settings. We planned to offer six courses (three intervention and three control), two in each province (control and intervention

simultaneously). Each course was a 45-minute lecture on DT2 and depression followed by 15 minutes to fill in the CPP-Reaction questionnaire. An additional 30 minutes was planned for the semi-structured group discussion.

Outcome Measures

We assessed three feasibility outcome measures: recruitment, retention and adherence: 1) recruitment of >90 course participants for six courses and study participation rate of >70% (24, 25), 2) retention of CPD organisations, collaborators and patient-partners throughout the project, 3) the holding of all planned CPD courses in all three provinces. Sample size was based on consultations with clinic managers and CPD providers and on practical considerations (e.g. average size of CPD courses, venues, the course being provided in French only).

We used CPD-Reaction (French version) to measure participants' behavioural intention to include sex and gender considerations in patient care. CPD-Reaction is a self-administered questionnaire (Cronbach α 0.79–0.89) (26, 27). Twelve items measure five constructs determined through a systematic review of theory-driven studies of behaviour change in health professionals: 1) behavioural intention, 2) beliefs about capabilities, 3) social influences, 4) beliefs about consequences, and 5) moral norm (24). The score for each construct is computed as the average of each item (Likert scale of 1 to 7), except for social influence, which is rated on a Likert scale of 1 to 5 (25). There is no global score. Finally, in group discussions, we identified barriers and facilitators to including sex and gender considerations in caring for patients with T2D and depression and mapped them onto the TDF. The TDF was developed through a consensus of experts who consolidated 33 psychosocial theories of behaviour change to generate 14 domains (28).

Data collection

Quantitative data were collected post-intervention with the CPD-Reaction questionnaire and sociodemographic questions (26). Semi-structured qualitative discussion took place in both intervention and control groups after the questionnaires were completed so as to not influence the quantitative results. In both intervention and control groups, discussions were recorded and transcribed.

Analysis

Quantitative analysis

Categorical variables were described by reporting absolute (n) and relative (%) frequencies. Continuous variables were described by their measure of central tendency (mean and/or median) and dispersion (standard deviation and percentiles). Covariance analysis was used to compare the scores of the intervention and control groups. As the intention did not have a perfectly Gaussian distribution, we also compared intention scores using Wilcoxon's non-parametric analysis and used the Kruskal-Wallis test to compare medians. We used Spearman's rank test to assess the correlation between the intention scores and psychosocial factors (social influence, beliefs about capacity, moral norms, beliefs about consequences). We used general linear models to assess whether the intention score varied significantly from the control group to intervention group after adjusting for confounding factors. These factors were identified using the 10% change in the regression coefficient associated with the exposure variable (29, 30). However, to increase the appearance validity of the model, we constructed a separate model in which we forced age, sex and practice environment. SAS software (version 9.4) was used for all statistical analyses. The empirical significance threshold (P value) was set at 0.05 in bilateral analysis.

Qualitative analysis

The discussion transcripts were imported into N'Vivo V.12 for analysis. Using the TDF as a guide, two researchers reviewed and agreed on codes and data were simultaneously coded using a thematic deductive approach (ADT, AGo) (31). Data were then refined into TDF domains. As the discussion occurred in French, all illustrative quotes were translated into English by a master's student (ADT) and reviewed by a scientific translator. We calculated the frequency of each barrier and facilitator by recording the number of times it was mentioned in the four group discussions (GDs 1 to 4).

Triangulating quantitative and qualitative data

We triangulated quantitative and qualitative data to propose practical theory-driven recommendations for improving our CPD intervention (32). We compared the five

psychosocial determinants measured in the CPD-Reaction questionnaire to the domains of the TDF. We observed where quantitative and qualitative data converged, where they offered additional information on the same constructs, and where they diverged. We derived recommendations using the COM-B model of behaviour (33). COM-B proposes three criteria essential for a behaviour to occur: capacity, opportunity and motivation (34). The subcategories of these criteria can be linked to the TDF domains and their associated barriers or facilitators (Supplementary Table 2). The COM-B also proposes nine intervention functions assigned to TDF domains that can prompt behaviour change: education, persuasion, incentivisation, coercion, training, restriction, environmental restructuring, modelling and enablement (33, 35, 36). Recommendations were made by identifying which of these intervention functions matched our results and then selecting relevant function-associated behaviour change techniques (33).

RESULTS

Recruitment and participant characteristics

We offered the 12 CPD courses (i.e. six intervention/control pairs) in each of three Canadian provinces: Quebec, Ontario and New Brunswick. Four pairs of courses were held in Quebec (two in Montreal, October 10th 2018 and October 30th 2019, and two in Quebec City, October 17th 2019 and January 29th 2019), one in Ontario (Ottawa, November 8th 2019) and one in New-Brunswick (Moncton, October 4th 2019).

Figure 1 illustrates the flow of participants. The participation rate (ratio of users who participated in the study to those who took the training) was 71% (127/178). Forty-nine of 92 questionnaires were analysed from the intervention groups and 78 of 86 from the control groups. Most participants were under 44 years old (n=80, 63%), female (n=101, 79.5%), practiced in French (n=86, 67.7%), in Quebec (n=85, 66.9%) and in an urban setting (n=100, 78.8%) (Table 1).

Table 1: Sociodemographic characteristics of the participants in intervention and control groups

	TOTAL	**Intervention Group**	**Control Group**

No. Of Participants	127	49	78
Age (years)*			
<44	80 (63.0)	28 (57.1)	52 (66.7)
≥ 45	42 (33.1)	19 (38.8)	23 (29.5)
Missing data	5 (3.9)	2 (4.1)	3 (3.8)
Sex*			
Female	101 (79.5)	40 (81.6)	61 (78.2)
Male	19 (15.0)	7 (14.3)	12 (15.4)
Missing data	7 (5.5)	2 (4.1)	5 (6.4)
Language of practice*			
French	86 (67.7)	32 (65.2)	54 (69.2)
Other	36 (28.3)	15 (30.6)	21 (26.9)
Missing data	5 (4.0)	2 (4.1)	3 (3.9)
Province of practice			
Quebec	85 (66.9)	31 (63.2)	54 (69.3)
Ontario	18 (14.2)	9 (18.4)	9 (11.5)
New Brunswick	16 (12.6)	7 (14.3)	9 (11.5)
Missing data	8 (6.3)	2 (4.1)	6 (7.7)
Practice environment*			
Urban	100 (78.8)	39 (79.6)	61 (78.2)
Rural	14 (11.0)	4 (8.2)	10 (12.8)

Missing data	13 (10.2)	6 (12.2)	7 (9.0)

*n(%) ;

Quantitative results

Feasibility

We recruited a total of 127 participants, a 41% increase from our target of 90 participants. Collaborators and executive committee members remained involved throughout the project. We held monthly executive committee meetings as planned. Our CPD trainings were held in the three provinces as planned. We gave 12 courses instead of the six initially planned, as more settings showed interest.

Behavioural Intention

Table 2 shows the scores of each psychosocial determinant in the CPD-Reaction questionnaire for both intervention and control groups. Mean difference between intervention and control scores for the four psychosocial determinants of behaviour change influencing intention were: MD=0.16 for social influence (95% CI: -0.26, 0.58), MD=0.63 for belief about capabilities (95% CI: 0.21, 1.06), MD=0.25 for moral norm (95% CI: -0.21, 0.72) and MD=0.22 for belief about consequences (95% CI: -0.23, 0.67). The mean intention score for including sex and gender considerations in patient care was higher in the intervention than in the control group, i.e. 5.65 (± 0.19) versus 5.19 (±0.15), on a scale from 1 (low) to 7 (high). The mean difference between the two groups was -0.47 (95% CI: -0.95, 0.01), with a p-value of 0.06 (**Supplementary table 1**). No statistically significant differences were observed for the remaining four psychosocial determinants. Bivariate analysis showed that the higher median for intention was significantly associated with age over 45 (p=0.03) and a rural practice environment (p=0.02) (**Supplementary table 1**). After adjusting for age, sex and practice environment, the mean difference in intention between the two groups was statistically significant: -0.57 (95% CI: -1.09, -0.05), with a p-value of 0.03 (**Table 3**).

Table 2: CPD-Reaction questionnaire mean scores

	Total	Intervention	Control	Difference (95% CI)
No. of participants	127	49	78	-
Psychosocial determinants – score range (1 to 7)*				
Social influence	4.62 (4.42; 4.83)	4.72 (4.44; 5,00)	4.56 (4.27; 4.85)	0.16 (-0.26; 0.58)
Beliefs about capabilities	5.1 (4.90; 5.33)	5.50 (5.27; 5.74)	4.87 (4.56; 5.17)	0.63 (0.21; 1.06)
Moral norm	5.90 (5.69; 6.13)	6.06 (5.80; 6.32)	5.81 (5.48; 6.14)	0.25 (-0.21; 0.72)
Beliefs about consequences	5.68 (5.46; 5.90)	5.82 (5.52; 6.11)	5.60 (5.28; 5.91)	0.22 (-0.23; 0.67)
Intention*	5.37 (5.13; 5.60)	5.65 (5.36; 5.95)	5.19 (4.85; 5.52)	0.47 (-0.01; 0.95)

*Mean (95% CI) ;

Table 3: Mean difference of the intention score between intervention and control groups

	Model 1*		Model 2†		Model 3‡	
	β (95% CI)	**P Value**	**β (95% CI)**	**P Value**	**β (95% IC)**	**P Value**
Control	Reference		Reference		Reference	
Intervention	-0.47 (-0.95;0.01)	**0.057**	-0.61 (-1.10;-0.12)	**0.015**	-0.57 (-1.09;-0.05)	**0.031**

95% CI, confidence interval at 95%;
*Non-ajusted;
†Ajusted for age and sex;
‡Ajusted for age, sex and environment of practice.

Qualitative findings

Due to time constraints imposed by CME settings, we held the group discussions in two out of the six settings, Montreal, October 30th 2019 and Ottawa, November 8th 2019. Thus four semi-structured group discussions (GD1, GD2, GD3, GD4) were conducted and 67 health professionals participated, reporting a variety of barriers and facilitators (**Table 4)**.

Table 4: Mapping facilitators and barriers to the Theoretical Domains Framework (TDF) with illustrative quotes and frequencies

TDF DOMAIN	FACILITATOR/ BARRIER	ILLUSTRATIVE QUOTES*	FREQUENCIES** (N=4 groups)
Skills	The health professional acknowledges different treatment methods by sex (Facilitator)	"Dominique, is that a man or a woman? … Because they are probably not treated the same" (GD4)	4
	The health professional acknowledges different clinical representation by sex (Facilitator)	"…I work as a nurse in cardiac and pulmonary rehabilitation, and … it is a fact, that women come less [to rehabilitation programs] in general than men. Women often will quit [rehabilitation] or they won't come because they're taking care of everyone. But something happens [illness] and then they don't have time to take care of themselves, because it's too much" (GD3)	1
	The health professional assumed the sex of the patient when analyzing a clinical vignette (Barrier)	"I assumed that it was a guy" (GD3) / "I presumed that it was a girl" (GD4)	3
Beliefs about Capabilities	The health professional feels he/she can accurately observe the phenotype of the patient (Facilitator)	"At the first contact we have with a patient … we see the phenotype there without talking about gender, it's one of the things that jumps out at you when you're taking notes." (GD3)	3
Social influences	The health professionals assume the patient's sex based on his/her societal role (Barrier)	"I heard 'civil servant', I don't know, in my head I was like 'civil servant', so it's a man." (GD4)	3

Knowledge	The health professional knows the differences between sex and gender in scientific literature (Facilitator)	"Yes, that's it actually, the biological aspect you certainly take into account in the study, but we are talking about [social] the categories of sex and gender… And menopause, and on the other hand [there's] also andropause" (GD2)	2
	The health professional did not ask the sex of the patient when analyzing a clinical vignette (Barrier)	"Well, I don't know why we didn't note it [the sex of the patient], I don't have the answer to that. But … when we talk about the clinical context it is systemically noted in the first … sentence, in the first two words [of notes documenting a consultation]. It's hard to say that we ignore it [sex of the patient]. We didn't notice it here, but in clinical practice, have you ever met a patient without identifying their gender?" (GD3)	2 1
		"…but in the seminar, there was no emphasis on that, so it didn't jump out at us," (GD3)	
	The health professional is not aware of the concepts of sex and gender when analyzing a clinical vignette (Barrier)		
Beliefs about Consequences	The health professional mentions that he/she would not change her/his therapeutic approach according to the patient's sex (Barrier)	"I would say that I didn't see the need to know if it was a man or a woman…I never asked myself the question..." (GD1)	2
Environmental Context and Resources	The patient's sex is routinely recorded in medical notes (Facilitator)	"… in the clinical context it's [the sex of the patient] systematically noted in the first lines in every consultation. In the first sentence, in the first two words. It's hard to say that we ignore it." (GD3)	2
	The androcentric nature of the French language (the use of masculine generic language to refer to men and women, as well as other gender representation) (Barrier)	"In French everything is masculine until you know, like in the room here [mostly women participants] we'll say like "ils ont fait ça" [*ils* is a masculine pronoun] because you are the only men, but…" [generalizing to the masculine pronoun] (GD3) / "The language doesn't help … [to differentiate between men and women]." (GD3)	1

	The healthcare professional perceives that the language used by physicians towards a patient may be different according to sex and gender (Barrier)	"Well it's about when you say 'our diabetes' and 'your depression', if it had been a woman would we have said the same thing?… 'your depression' 'our diabetes'..." (GD2) [referring to the bias in the language to describe 'your' depression versus 'our' diabetes]	1
Social/Professional Role and Identity	The health professional reflects positively on his/her relationship with the patient (Facilitator)	"I work in an exclusively white environment, and I am the only black person, and I have no problem whether [the patient] is male, female or a child" (GD3)	1
Intentions	The health professional has the intention to change his/her therapeutic approach by considering the differences of sex (Facilitator)	"With the information that I have here [clinical description of vignette], if I had 'menopaused woman', then I think I would have researched more, but with what I had here, I didn't [see the need]." (GD4)	1
	The health professional does not have the intention to change his/her therapeutic approach by considering the differences of sex (Barrier)	"With what I have here [descriptive information of the clinical vignette], I am not sure to what extent I would have changed my approach" (GD4)	1
Goals	The health professional does not perceive the integration of the concepts of sex and gender in clinical practice as a priority (Barrier)	"It wasn't important … the most important, [but] that doesn't mean that [the lack of sex and gender consideration in the clinical vignette] wasn't perceived" (GD4)	1
Memory, Attention and Decision Processes	The health professional does not consider that sex and gender are necessary parts of the decision-making process (Barrier)	"If it is not obvious, we are not inclined to do it… [take into consideration the sex and gender of the patient]" (GD2)	1

*Free translation from French

**The number of times that the barrier/facilitator appeared in the transcript

Barriers mapped to the TDF domains

Ten barriers mapped to nine of the 14 TDF domains. Skills and social influence were the most frequent domains (n=3) (**Table 4**). We mapped barriers to skills when participants assumed the sex of the patient in the vignette without asking. Barriers were mapped to social influence when participants assumed the sex of the patient based on a social trait, such as employment. We mapped barriers to knowledge when participants did not show awareness that the patient's sex was relevant, i.e. simply did not ask about it. We also mapped barriers to knowledge when participants reported they did not take sex and gender into account because the CPD training did not suggest it was necessary. When participants reported not needing to know the patient's sex because this information would not have changed their intervention, we mapped the barrier to beliefs about consequences. Other barriers mapped to six other domains. Finally, when asked why they didn't identify lack of sex and gender as the main inconsistency in the clinical vignette, most participants responded that it was less important than other inconsistencies in the clinical practice of the fictitious physician.

Facilitators mapped to the TDF domains

Seven facilitators mapped onto six of the 14 TDF domains (**Table 4**). When participants asked the sex of the patient before analysing the clinical vignette, we mapped it onto skills (n=4), as it demonstrated they did not assume the sex or gender of the patient and awareness that they should consider sex and gender before clinical analysis. Participants documented some differences between men and women patients in their clinical practice, demonstrating ability acquired through practice to include sex and gender considerations. Participants also reported they did not ask the sex of the patient in the clinical vignette as they automatically observe a patient's sex in practice, so didn't feel the need to mention it in this context. This facilitator was mapped to the domain beliefs about capabilities (n=3). Some participants reported that they routinely observe and record a patient's sex when taking notes. This facilitator was mapped to the domain environmental context and resources, since it this is an institutional practice reflecting an organisational clinical culture, and could foster further awareness and consideration of sex and gender.

Other facilitators were mapped to knowledge, intention, and social/professional role and identity (**Table 4**).

Triangulation

CPD-Reaction psychosocial variables matched barriers that mapped onto to the TDF domains beliefs about consequences, social influence and intentions. CPD-Reaction psychosocial variables also matched facilitators that mapped onto to the TDF domains beliefs about capabilities and intentions. We identified six additional psychosocial variables from the TDF: knowledge, skills, goal, memory, attention and decision processes, environmental context and resources, social/professional role and identity. Results of triangulation were summarised with consequent recommendations (**Supplementary table 2)**. Recommendations for improving the CPD training were based on behaviour change techniques associated with the following functions: modelling, training, environmental restructuring, enablement, education and goal settings (**Supplementary table 2)**. Training (n=5) and education (n=4) were the most frequent functions used in the recommendations.

DISCUSSION

We assessed the feasibility and impact of including sex and gender considerations in a CPD course on T2D and depression care, on health professionals' intention to include sex and gender considerations in patient care. Recruited CPD organisations, collaborators and patient-partners stayed engaged throughout the study. All planned activities occurred and 71% of targeted health professionals participated. The intention to include sex and gender considerations in patient care was higher in the intervention group, and statistically significant when controlling for age, sex, and practice sites. Barriers were mostly related to skills and social influence and facilitators to skills and beliefs about capabilities. We triangulated results and produced for improving the CPD course. The following observations could enable CPD organizations to systematically improve CPD by integrating sex and gender considerations into their existing material.

First, all our predetermined feasibility criteria were met. In fact, due to increased interest in the topic, we recruited more participants and gave more CPD activities than planned. Recruitment may also have improved because we involved stakeholders early on in the research process, including in applying for the grant. Early engagement of stakeholders has been associated elsewhere with more successful recruitment (37). Therefore, elements that should be considered when designing similar CPD activities include, but are not limited to:

1) successful collaboration and co-creation with CPD organizations early on including during grant writing, 2) offering CME accreditation for the CPD activities allowing participants to earn CME credits, 3) the duration for the training, and 4) the evidence-based relevant to the clinical topic (38).

Second, the CPD course that included sex and gender considerations increased health professionals' intention to include sex and gender considerations in patients' care. This may suggest a significant knowledge gap among participants. Studies show that health professionals lack knowledge of sex and gender differences in disease manifestation and outcomes and fail to recognize the gender constraints that their patients face (39-42). For example, in a cross-sectional survey of physicians (71% male), 55% said that the medical curriculum did not adequately prepare them for dealing with sexual health problems, particularly those of female patients (39). In another study, only 49% of primary care physicians (n=200, 65% male) and 59% of cardiologists (n=100, 85% male) reported that their training prepared them to assess female patients' cardiovascular risk (41). Our study represents a promising avenue for rectifying these gaps. Furthermore, the effectiveness of our CPD course was greater among older participants from rural sites. Their age and geographical isolation perhaps reduced their exposure to sex and gender issues, which have only been included in medical curricula since they qualified (42). They may also have less access to CPD training due to isolation, poor technological resources, low financial support (43, 44) and geographical variations in medical practice styles (45, 46). Future studies could further investigate the perceptions of health professionals in rural settings considering their age and sex. They could also document if patients experience geographical differences in care regarding sex and gender. Training could target older and rural health professionals, who seemed more open to modifying their clinical practice.

Third, several barriers and facilitators to considering sex and gender in patient care were identified. These semi-structured group discussions using a clinical vignette may be considered as reinforcing activities which have be shown to contribute to clinical behavior change (47). Whilst measuring heath professionals' behavior to analyze its relationship with intention is not easily attainable but identifying barriers and facilitators to behaviour change is a necessary first step (47). Beliefs about capabilities as a facilitator showed the

strongest mean difference between the intervention and control groups. Adding a practical component to the CPD course may strengthen beliefs about capabilities. However, our qualitative analysis showed that participants did not consider integrating sex and gender into clinical practice as a priority, with social influences emerging as an important barrier. The social influence score as measured by CPD-Reaction also showed the lowest impact (MD=0.16), suggesting that the training did not address this factor (Table 2). A CPD course could offer a reflective segment on how social influence could be affecting their clinical practice (46, 48). Furthermore, belief about consequences had one of the lowest MD (0.22) of the five psychosocial determinants, and one associated barrier (n=2 participants), and could be remedied by focusing more on the consequences of not integrating sex and gender into clinical practice (40). In spite of the low priority given to sex and gender by our participants, qualitative analysis demonstrated that opportunities already exist for integrating these considerations into practise, such as the routine documenting of the patient's sex. CPD strategies could make more of these opportunities (49). CPD courses could also incorporate sex- and gender-based analysis tools (50).

Our study has a few limitations. As we used a single post-intervention measure, we cannot attribute the difference between the two groups solely to the intervention. However, our analysis suggests that those who completed the intervention increased their intention, as well as increasing all four psychosocial predictors, suggesting an association with the intervention. Second, although the human resources for both groups were the same (trainer, research-assistant and patient-partners), the control group had an extra team member resulting in unequal numbers of participants who signed consent in each group. The presence of this extra member could also explain the difference in the number of questionnaires collected in the two groups. Lastly, our discussion groups attracted many participants, limiting both participants' opportunity to speak and the depth of the discussion. Our mixed-methods approach is a strength of this study and our findings support the feasibility of a randomized trial informed by identified barriers and facilitators.

CONCLUSION

A CPD course with sex and gender considerations is feasible, well received by health professionals and had a favourable impact on health professionals' intention to include

sex and gender considerations in caring for individuals with T2D and depression. The impact was higher on older participants practising in rural areas. However, several barriers and facilitators to providing sex- and gender-adapted diabetes and depression care will need to be addressed. Our findings will inform future CPD initiatives that address this and other inequities in health care pertaining to sex and gender.

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ADT, AGo, SGB and FL conceived, designed and drafted the manuscript. NP, DA, AGa, DRL, LV and GN critically revised the interpretation of data. All authors and members of the mATrICES-F Group read, provided feedback and approved the final manuscript.

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Disclaimer

The findings and views are those of the authors.

Competing interests

None declared.

Patient consent for publication

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References

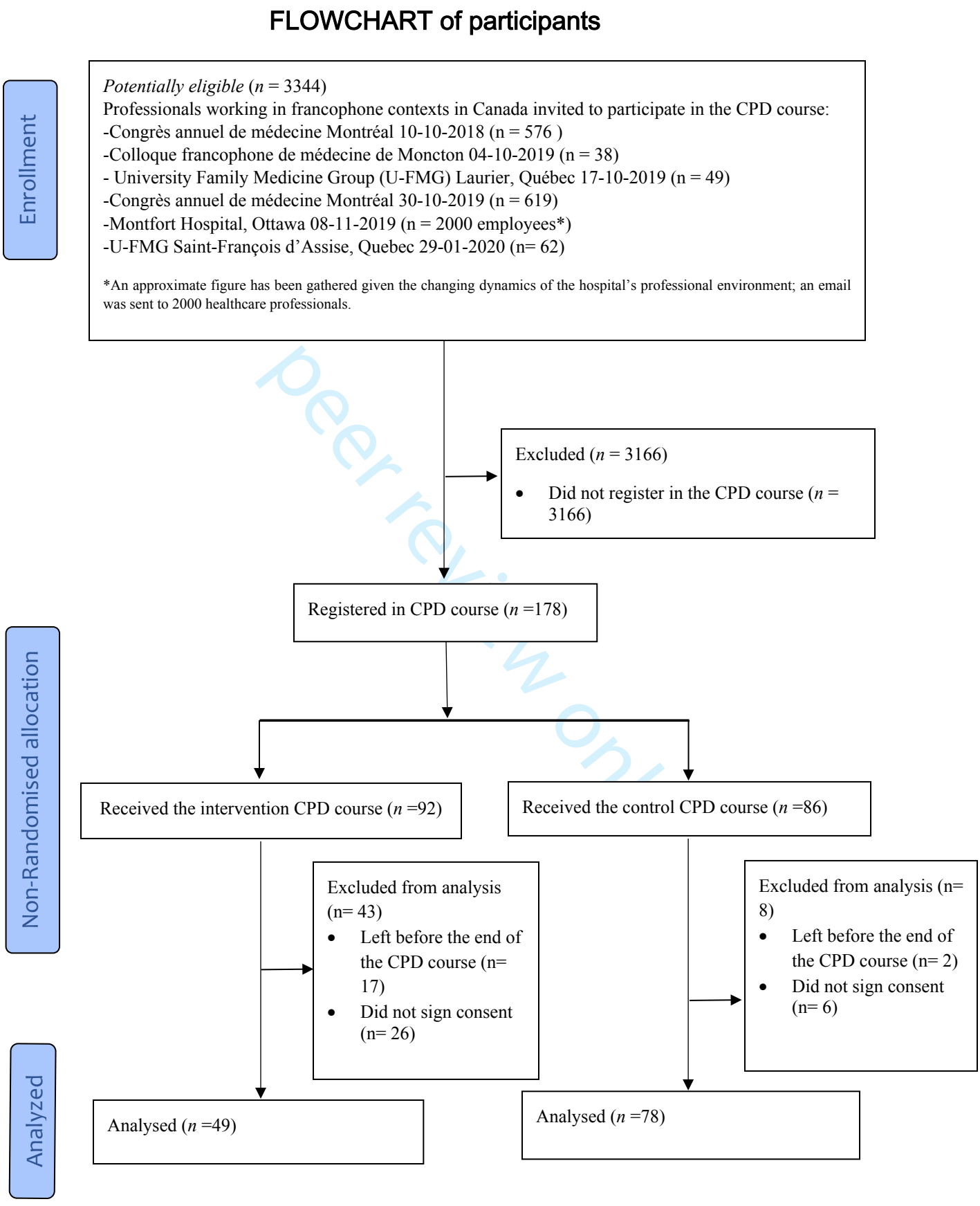
1. Clayton JA, Tannenbaum C. Reporting Sex, Gender, or Both in Clinical Research? JAMA. 2016;316(18):1863.
2. Institut de recherche en santé du Canada. Comment intégrer le sexe et le genre à la recherche 2019 [Available from: http://cihr-irsc.gc.ca/f/50836.html.
3. Johnson JL, Greaves L, Repta R. Better science with sex and gender: Facilitating the use of a sex and gender-based analysis in health research. International Journal for Equity in Health. 2009;8(1):14.
4. Oliffe J, Greaves L. Designing and Conducting Gender, Sex, and Health Research. Thousand Oaks, California2012. Available from: http://sk.sagepub.com/books/designing-and-conducting-gender-sex-and-health-research.
5. Légaré F, Lee-Gosselin H, Borduas F, Monette C, Bilodeau A, Tanguay D, et al. Approaches to considering sex and gender in continuous professional development for health and social care professionals: An emerging paradigm. Medical Teacher. 2018;40(9):875-9.
6. Tannenbaum C, Ellis RP, Eyssel F, Zou J, Schiebinger L. Sex and gender analysis improves science and engineering. Nature. 2019;575(7781):137-46.

7. Kautzky-Willer A, Harreiter J, Pacini G. Sex and gender differences in risk, pathophysiology and complications of type 2 diabetes mellitus. Endocrine reviews. 2016;37(3):278-316.
8. Geary N. Counterpoint: physiologists should not distinguish "sex" and "gender". American Journal of Physiology-Regulatory, Integrative and Comparative Physiology. 2010;298(6):R1702-R4.
9. Demmer RT, Gelb S, Suglia SF, Keyes KM, Aiello AE, Colombo PC, et al. Sex Differences in the Association Between Depression, Anxiety, and Type 2 Diabetes Mellitus. 2015;77(4):467-77.
10. Kuehner C. Why is depression more common among women than among men? Lancet Psychiatry. 2017;4(2):146-58.
11. Turecki G, Brent DA. Suicide and suicidal behaviour. The Lancet. 2016;387(10024):1227-39.
12. Ryba MM, Hopko DR. Gender Differences in Depression: Assessing Mediational Effects of Overt Behaviors and Environmental Reward through Daily Diary Monitoring. Depression Research and Treatment. 2012;2012:865679.
13. Schmid SM, Hallschmid M, Schultes B. The metabolic burden of sleep loss. Lancet Diabetes Endocrinol. 2015;3(1):52-62.
14. Li L, Wu C, Gan Y, Qu X, Lu Z. Insomnia and the risk of depression: a meta-analysis of prospective cohort studies. BMC Psychiatry. 2016;16(1):375.
15. Tannenbaum C, Clow B, Haworth-Brockman M, Voss P. Sex and gender considerations in Canadian clinical practice guidelines: a systematic review. CMAJ Open. 2017;5(1):E66-E73.
16. Ferlie EB, Shortell SM. Improving the quality of health care in the United Kingdom and the United States: a framework for change. Milbank Q. 2001;79(2):281-315.
17. Davis D, Evans M, Jadad A, Perrier L, Rath D, Ryan D, et al. The case for knowledge translation: shortening the journey from evidence to effect. Bmj. 2003;327(7405):33-5.
18. Davis D, Galbraith R. Continuing Medical Education Effect on Practice Performance. Chest. 2009;135(3):42S-8S.
19. Institute of Medicine. Redesigning Continuing Education in the Health Professions. Washington, DC: The National Academies Press; 2010. 296 p.
20. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355:i5239.
21. Gogovor A MT, Etherington N, Colantonio A, Légaré F, on behalf of the GIKT Group. Sex and gender analysis in knowledge translation interventions: challenges and solutions. Health Research Policy and Systems. 2020;18(1):108.
22. Atlantis E, Fahey P, Foster J. Collaborative care for comorbid depression and diabetes: a systematic review and meta-analysis. BMJ Open. 2014;4(4):e004706.
23. Holt RI, de Groot M, Golden SH. Diabetes and depression. Curr Diab Rep. 2014;14(6):491.
24. Légaré F, Freitas A, Turcotte S, Borduas F, Jacques A, Luconi F, et al. Responsiveness of a simple tool for assessing change in behavioral intention after continuing professional development activities. PLOS ONE. 2017;12(5):e0176678.

25. Légaré F, Borduas, F., Freitas, A., Turcotte, S. User Manual – The Continuing Professional Development (CPD) Reaction Questionnaire. 2015.
26. Légaré F, Borduas F, Freitas A, Jacques A, Godin G, Luconi F, et al. Development of a Simple 12-Item Theory-Based Instrument to Assess the Impact of Continuing Professional Development on Clinical Behavioral Intentions. PLoS ONE. 2014;9(3):e91013.
27. Godin G, Bélanger-Gravel A, Eccles M, Grimshaw J. Healthcare professionals' intentions and behaviours: A systematic review of studies based on social cognitive theories. Implementation Science. 2008;3(1):36.
28. Michie S. Making psychological theory useful for implementing evidence based practice: a consensus approach. Quality and Safety in Health Care. 2005;14(1):26-33.
29. Mickey R M GS. The Impact of Confounder Selection Criteria on Effect Estimation American Journal of Epidemiology. 1989;129(1):125-37.
30. Budtz-Jørgensen E, Keiding N, Grandjean P, Weihe P. Confounder selection in environmental epidemiology: assessment of health effects of prenatal mercury exposure. Ann Epidemiol. 2007;17(1):27-35.
31. Atkins L, Francis J, Islam R, O'Connor D, Patey A, Ivers N, et al. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. Implement Sci. 2017;12(1):77.
32. O'Cathain A, Murphy E, Nicholl J. Three techniques for integrating data in mixed methods studies. Bmj. 2010;341:c4587.
33. Michie S, Atkins L, R. W. The behaviour change wheel : a guide to designing Interventions. Great Britain: Silverback Publishing; 2014.
34. West R, Michie S. A brief introduction to the COM-B Model of behaviour and the PRIME Theory of motivation. Qeios. 2020.
35. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. Implementation Science. 2011;6(1):42.
36. Agbadjé TT, Menear M, Dugas M, Gagnon M-P, Rahimi SA, Robitaille H, et al. Pregnant women's views on how to promote the use of a decision aid for Down syndrome prenatal screening: a theory-informed qualitative study. BMC Health Services Research. 2018;18(1).
37. Garvelink MM, Freitas A, Menear M, Brière N, Stacey D, Légaré F. In for a penny, in for a pound: the effect of pre-engaging healthcare organizations on their subsequent participation in trials. BMC Research Notes. 2015;8(1):751.
38. Little P, Hayes S. Continuing professional development (CPD): GPs' perceptions of post-graduate education-approved (PGEA) meetings and personal professional development plans (PDPs). 2003;20(2):192-8.
39. Veloshnee G, Loveday P-K. Gender biases and discrimination: a review of health care interpersonal interactions 2007 [Available from: https://www.who.int/social_determinants/resources/gender_biases_and_discrimination_wgkn_2007.pdf.
40. Mauvais-Jarvis F, Bairey Merz N, Barnes PJ, Brinton RD, Carrero J-J, Demeo DL, et al. Sex and gender: modifiers of health, disease, and medicine. The Lancet. 2020;396(10250):565-82.

41. Bairey Merz CN, Andersen H, Sprague E, Burns A, Keida M, Walsh MN, et al. Knowledge, Attitudes, and Beliefs Regarding Cardiovascular Disease in Women: The Women's Heart Alliance. J Am Coll Cardiol. 2017;70(2):123-32.
42. Kling JM, Rose SH, Kransdorf LN, Viggiano TR, Miller VM. Evaluation of sex- and gender-based medicine training in post-graduate medical education: a cross-sectional survey study. Biology of Sex Differences. 2016;7(S1).
43. Curran VR, Fleet L, Kirby F. Factors influencing rural health care professionals' access to continuing professional education. Aust J Rural Health. 2006;14(2):51-5.
44. Berndt A, Murray CM, Kennedy K, Stanley MJ, Gilbert-Hunt S. Effectiveness of distance learning strategies for continuing professional development (CPD) for rural allied health practitioners: a systematic review. BMC Medical Education. 2017;17(1).
45. OCDE. Geographic Variations in Health Care2014.
46. Bertakis KD, Helms LJ, Callahan EJ, Azari R, Robbins JA. The influence of gender on physician practice style. Med Care. 1995;33(4):407-16.
47. Eccles MP, Hrisos S, Francis J, Kaner EF, Dickinson HO, Beyer F, et al. Do self-reported intentions predict clinicians' behaviour: a systematic review. Implementation Science. 2006;1(1).
48. Etherington N, Rodrigues IB, Giangregorio L, Graham ID, Hoens AM, Kasperavicius D, et al. Applying an intersectionality lens to the theoretical domains framework: a tool for thinking about how intersecting social identities and structures of power influence behaviour. BMC Medical Research Methodology. 2020;20(1).
49. Guly HR. Continuing professional development for doctors in accident and emergency. Journal of Accident & Emergency Medicine. 2000;17(1):12-4.
50. Macdermid JC, Graham ID. Knowledge Translation: Putting the “Practice” in Evidence-Based Practice. Hand Clinics. 2009;25(1):125-43.

Figure 1 Flowchart of participants



Supplementary table 1: Distribution of the scores of intention to include sex and gender considerations in patient care in the clinical context of T2D and depression

	Parametric estimation *				**Non-parametric estimation**†		
	Intervention	Control	Mean difference (95% CI)	*P*Value‡	Intervention	Control	*P* Value£
No. of participants	49	78			49	78	
Total	5.65±0.19	5.19±0.15	-0.47 (-0.95; 0.01)	0.057	5.50 (5.00; 6.50)	5.50 (4.50; .00)	0.162
Age (years)							
< 44	5.68±0.25	5.30±0.18	-0.38 (-1.00; 0.24)	0.226	5.50 (5.00; 6.50)	5.50 (5.00; 6.50)	0.717
≥ 45	5.92±0.29	4.93±0.26	-0.99 (-1.78; -0.20)	**0.016**	6.00 (5.00; 6.50)	5.50 (3.50; 6.00)	**0.029**
Sex							
Men	5.79±0.45	4.79±0.34	-0.99 (-2.19; 0.20)	0.098	6.00 (5.00; 6.50)	5.25 (3.50; 6.00)	0.070
Women	5.78±0.21	5.24±0.17	-0.54 (-1.08; 0.00)	0.051	5.50 (5.00; 6.50)	5.50 (4.50; 6.50)	0.245
Language							
French	5.81±0.20	5.35±0.16	-0.46 (-0.97; 0.05)	0.073	6.00 (5.00; 6.50)	5.50 (4.50; 6.00)	0.133
Other	5.70±0.42	4.76±0.35	-0.94 (-2.05; 0.17)	0.096	5.50 (5.00; 6.50)	5.50 (4.50; 6.00)	0.346
Province of practice							
Quebec	5.85±0.20	5.43±0.15	-0.43 (-0.94; 0.08)	0.097	6.00 (5.00; 6.50)	5.50 (5.00; 6.50)	0.144
Ontario	5.83±0.43	4.89±0.43	-0.94 (-2.23; 0.34)	0.138	6.00 (5.00; 6.50)	5.00 (4.50; 6.00)	0.223
New Brunswick	5.36±0.73	4.00±0.64	-1.36 (-3.44; 0.72)	0.184	5.50 (5.00; 5.50)	4.00 (1.00; 6.00)	0.512
Environment of practice							

Urban	5.74±0.20	5.37±0.16	-0.37 (-0.88; 0.13)	0.143	5.50 (5.00; 6.50)	5.50 (5.00; 6.50)	0.486
Rural	6.38±0.87	4.45±0.55	-1.93 (-4.17; 0.32)	0.086	6.25 (6.00; 6.75)	5.25 (3.50; 6.00)	**0.018**

*Mean±standard deviation;
†Median (25th percentile; 75th percentile);
‡Derived from the general linear models;
£Derived from the Kruskal-Wallis (Wilcoxon) test

Supplementary table 2: Recommendations for improving the CPD training, based on barriers and facilitators, using the COM-B model, the Theoretical Domains Framework and the CPD-Reaction questionnaire

COM-B criteria	COM-B criteria subcategory	TDF domains linked to COM-B	Barriers and facilitators perceived by health professionals to including sex and gender considerations in their clinical practice	Psychosocial determinants of the CPD-Reaction questionnaire	Recommendations (COM-B Intervention function)
Opportunity					
	Social	Social influence	Health professionals assume the patient's sex based on his/her societal role (Barrier)	Social influence	In the CPD course, a clinical case vignette could demonstrate the integration of sex and gender considerations and reflect on the different social stigmas associated with gender (Modelling)
	Physical	Environmental context and resources	The patient's sex is already recorded in medical notes (Facilitator)		CPD training could expand on routine practices that already include sex and gender in clinical practice, example: recording sex, but going further by asking questions about perceived gender, sexual orientation (Training)
			The androcentric nature of the French language (the use of masculine generic language to refer to men and women, as well as other gender representations) (Barrier)		CPD training could give prompts/cues to demonstrate sex- and gender-sensitive medical language (e.g. revised forms, gender sensitive formulation of questions on sexuality and relationships) to promote equity in clinical practice (Environmental restructuring) The CPD training could encourage health professionals to self-monitor their use of gender inclusive language (Training/Enablement)
			The healthcare professional perceives that the language used by physicians towards a patient may be		CPD training could demonstrate sex- and gender-sensitive behaviours and patterns of speech through video animations of clinical visits between health professionals and their

			different according to sex and gender (Barrier)		patients, as well as showing various health professional and patient scenarios (Training)
Motivation					
	Reflective	Social and professional role and identity	The health professional reflects positively on his/her relationship with the patient (Facilitator)		
		Beliefs about capabilities	The health professional feels he/she can accurately observe the phenotype of the patient (Facilitator)	Beliefs about capabilities	Self-monitoring of behaviour to encourage health professionals to analyse how they record patient phenotypes: what do they take into consideration? Do they ask specific questions or is it strictly observational? (Enablement)
		Intentions	The health professional has the intention to change his/her therapeutic approach by considering the differences of sex (Facilitator)	Intention	Enable health professionals to change their behaviour by demonstrating strategies they have already undertaken to consider the sex of the patient during their therapeutic approaches (Modelling)
			The health professional does not have the intention to change his/her therapeutic approach by considering the differences of sex (Barrier)		Offer information about social consequences of not modifying their care to include sex and gender considerations (Education) Offer information about health consequences of not modifying their care to include sex and gender considerations (Education)
		Goals	The health professional does not perceive the integration of the concepts of sex and gender in clinical practice as a priority (Barrier)		Enable participants to engage in action planning to include sex and gender considerations in their clinical practice, as well as implementation intentions (Enablement) Enable participants to engage in specific goal setting on how

					they would include sex and gender considerations in their clinical practice (Goal setting)
		Beliefs about consequences	The health professional mentions that he/she would not change her/his therapeutic approach according to the patient's sex (Barrier)	Beliefs about consequences	Offer CPD content with credible sources about the health consequences of not modifying their care to include sex and gender considerations (Education) Demonstration of various techniques, shared decision making, cues and prompts that include sex and gender considerations in care (Modelling)
Capability					
	Psychological	Memory, Attention and Decision Processes	The health professional perceives that sex and gender are not systematic in the decision-making process (Barrier)		Offer specific training to create routine and habit formation that encourages the systematic inclusion of sex and gender considerations in the decision-making process (Training)
		Cognitive and interpersonal skills	The health professional does not assume the sex of the patient and acknowledges different treatment methods by sex (Facilitator)		
			The health professional acknowledges different clinical representation by sex (Facilitator)		
			The health professional assumed the sex of the patient when analysing a clinical vignette (Barrier)		As part of skills training, the CPD training could demonstrate how to explore the different aspects of sex attribution, without assuming the sex of the patient (Training) Give specific instructions on how to explore the different aspects of sex attribution,

					without assuming the sex of the patient (Training) Offer feedback on outcome(s) of assuming the sex of the patient in a clinical case vignette (Training) Offer a practice/rehearsal period after receiving instructions on how to explore the different aspects of sex attribution, without assuming the sex of the patient (Training)
		Knowledge	The health professional recognizes the differences between sex and gender in scientific literature (Facilitator)		
			The health professional did not ask the sex of the patient when analyzing a clinical vignette (Barrier)		Include information on the possible clinical outcome(s) of assuming the wrong sex or gender of the patient (Education)
			The health professional is not aware of the concepts of sex and gender (Barrier)		Offer information about health consequences of not considering or confusing sex and gender terms (Education)

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1 (mixed methods)
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	7-8
	2b	Specific objectives or research questions for pilot trial	8
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	8
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	17
Participants	4a	Eligibility criteria for participants	9
	4b	Settings and locations where the data were collected	9-10
	4c	How participants were identified and consented	9-10
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9-10-11
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	11
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	NA
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	NA
Sample size	7a	Rationale for numbers in the pilot trial	11
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	NA
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	NA
Allocation concealment	9	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	NA

mechanism			
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	10
	11b	If relevant, description of the similarity of interventions	10
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	12-13
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	13
	13b	For each group, losses and exclusions after randomisation, together with reasons	13
Recruitment	14a	Dates defining the periods of recruitment and follow-up	13
	14b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	14
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	15
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	15-16
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
	19a	If relevant, other important unintended consequences	NA
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	23
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	23
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	21-22
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	23
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	5
Protocol	24	Where the pilot trial protocol can be accessed, if available	NA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	25
	26	Ethical approval or approval by research review committee, confirmed with reference number	26

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Integration of Sex and Gender in a Continuing Professional Development Course on Diabetes and Depression: A Mixed Methods Feasibility Study

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Integration of Sex and Gender in a Continuing Professional Development Course on Diabetes and Depression: A Mixed Methods Feasibility Study

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Abstract

Objectives Assess the feasibility and impact of a continuous professional development (CPD) course on type-2 diabetes and depression on health professionals' intention to include sex and gender considerations in patient care.

Design and setting In collaboration with CPD organisations and patient-partners, we conducted a mixed-methods feasibility controlled trial with post-intervention measures in three Canadian provinces.

Participants Of 178 eligible health professionals, 127 completed questionnaires and 67 participated in semi-structured group discussions.

Intervention and comparator An interactive one-hour CPD course, co-designed with patient-partners, on diabetes and depression with sex and gender considerations (intervention) was compared to a similar course without these considerations (comparator).

Outcomes Feasibility of recruitment and retention of CPD organisations and patient-partners throughout the study; adherence to planned activities; health professionals' intention to include sex and gender considerations in patient care as measured by the CPD-Reaction questionnaire; and barriers and facilitators using the Theoretical Domains Framework.

Results All recruited CPD organisations and patient-partners remained engaged throughout the study. All planned CPD courses occurred. Overall, 71% of eligible health professionals participated (63% under 44 years old; 79.5% women; 67.7% practising in French; 66.9% practising in Quebec; 78.8% in urban practice). After training, mean intention scores for the intervention (n=49) and control groups (n=78) were 5.65 ± 0.19 and 5.19 ± 0.15, respectively. Mean difference was -0.47 (CI -0.95 to 0.01; p=0.06). Adjusted for age, gender and practice settings, mean difference was -0.57 (CI -1.09 to -0.05; p=0.03). We identified eight Theoretical Domains related to barriers and six related to facilitators for providing sex- and gender-adapted diabetes and depression care.

Conclusions CPD training on diabetes and depression that includes sex and gender considerations is feasible and, compared to CPD training that does not, may prompt health

professionals to modify their care. Addressing identified barriers and facilitators could increase intention.

Registration number: NCT03928132 with ClinicalTrials.gov.

Keywords: Sex and gender, knowledge translation, continuous professional development, diabetes, depression, patient engagement, Theory of Planned Behaviour, Theoretical Domains, COM-B

Strengths and limitations of this study

- Continuous professional development (CPD) courses that included sex and gender considerations were co-designed with patients experiencing diabetes and/or depression.
- Outcome measures were informed by theory.
- This mixed-methods controlled trial used post-intervention measures only, as pre-intervention measures were not feasible. Although randomized allocation of participants was not possible, it was feasible to conduct a mixed-methods controlled trial.

INTRODUCTION

A variety of research initiatives are attempting to reduce health inequities between men and women (1, 2). Research that includes sex- and gender-based analysis results in more accurate evidence, more relevant recommendations, more specifically-targeted interventions, and better outcomes (3-6). Sex differences are biology-linked differences between females and males caused by different sex chromosomes, sex-specific gene expression of autosomes, sex hormones, and their effects on organ systems (7). Gender differences arise from sociocultural processes such as the different behaviours of women and men, their exposure to environmental influences, impacts of nutrition, lifestyles or stress, and attitudes towards illness, treatment and prevention (7). Gender roles and gender identity are influenced by a complex interplay between genetic, endocrinal, and social factors (8). Finally, sex and gender are not straightforward binary categories. Many femininities and masculinities exist and can influence other important sociodemographic variables (9).

During their lifetime women are twice as likely as men to be diagnosed with depression. In contrast, three times as many men commit suicide (5, 10, 11). Recent evidence supports a link between type 2 diabetes (T2D) and depression, and shows that sex and gender are influential factors in this comorbidity (7, 9). The prevalence of depression in diabetic patients is higher in females than males (23.8% and 12.8%, respectively) (7). On the other hand, a pooled result from 32 studies described that the risk of developing T2D in patients diagnosed with depression is higher in men than in women (RC=1.63 vs RC=1.29, respectively) (7, 12, 13). The differences are explained by biological differences and psychosocial factors such as body mass index, differences in the distribution of types of adipose tissue, an imbalance of sex hormones, socioeconomic status, psychosocial stress, and sleep deprivation (7, 9). Co-morbidity and mortality associated with the complications of T2D and depression are also different for men and women. For instance, men develop diabetic food syndrome at earlier ages and are more likely to have complications leading to amputations (7, 14). Women, on the other hand, have a higher risk of metabolic syndrome and fatal coronary heart disease than men (7, 15, 16). T2D and depression are also affected by gender differences. This gap could be explained in part by the different

behaviours associated gender representations of men and women, as well as their different perceptions of stress (17-19).

Despite the impacts of sex and gender differences on prevalence, diagnosis, treatment, outcomes, and equity, evidence on the importance of these differences has yet to be translated adequately into clinical training or practice (2, 5, 20). For example, a 2017 review suggested that only 35% of studies on Canadian practice guidelines, a cornerstone of knowledge translation, reported screening, diagnosis or management considerations specific to sex or gender, and only 25% used the terms "sex" and "gender" correctly (21).

Continuing professional development (CPD) is another cornerstone of knowledge translation as it mobilizes professional and regulatory bodies as well as educational institutions to foster changes in clinical practice (22, 23). We argue that integrating sex and gender considerations into CPD is a promising avenue for addressing the inequities between men and women (5). We define CPD as all educational activities serving to maintain or increase the knowledge, skills, work performance, and relationships that a clinician needs to serve patients, the public or the profession. (5, 24, 25). Courses should be informed by theory-based factors known to influence the adoption of a given behaviour. Although one of several other factors influencing behaviour change, such as organizational constraints, intention is considered an acceptable proxy. Indeed, according to Godin's integrated model for health professional behaviour change, behavioral intention is the central influencing factor on behaviour adoption. In turn, this intention is under the influence of a number of other socio-cognitive factors (26). We aimed to assess the feasibility and impact of including sex and gender considerations in a CPD course on T2D and depression on health professionals' intention to include sex and gender considerations in patient care.

METHODS

Study design and setting

We conducted a non-randomized mixed-methods study with a concurrent embedded design: (1) a two-arm non-randomized controlled trial with post-intervention measures only; and (2) semi-structured group discussions following the CPD course. We used the

Theory of Planned Behavior for quantitative analysis (27, 28), the Theoretical Domains Framework (TDF) for qualitative analysis (29, 30), and the COM-B (Capability, Opportunity, Motivation and Behavior) model to triangulate findings (31). We followed the CONSORT extension for Pilot and Feasibility Trials Checklist to report results (32).

This project is one of six that were funded by the Canadian Institutes of Health Research to explore sex and gender issues in knowledge translation (33), gender transformative approaches to knowledge translation, and sex- and gender-based analysis (5, 33).

A multidisciplinary team was created of 25 researchers: two sex and gender specialists, three patient-partners with experience with T2D and/or mental health issues (two men and one woman), two physicians, one nurse, two CPD managers, one research assistant and two trainees. An executive committee of 12 team members (including all patient-partners) held monthly meetings addressing the main concerns in each research phase. They chose the clinical topic of the course based on needs expressed by CPD providers (see Intervention below). They then adapted an existing diabetes and depression CPD course to include sex and gender considerations and contacted CPD providers in three Canadian provinces to collaborate on implementing the courses.

Patient involvement

Three patient-partners, core members of the executive committee, contributed to governance (e.g., attending meetings and courses, making executive decisions) and intervention design. They contributed their experience to the CPD course, helped collect data and interpret results, coauthored this paper and advised us on plain language use for our presentations.

Participants and recruitment

All health professionals working in the clinical settings where our CPD course was advertised, including hospitals and family medicine groups, or participating in the continuing medical education (CME) conference where the course was to be offered, were invited to participate. Invitations were by email and through the Internet registration platforms of CME conferences in three Canadian provinces (Quebec, Ontario, New-Brunswick). Participants stayed in their respective groups for the semi-structured group

discussion that immediately followed the CPD course. Inclusion criteria were: practising health professionals available to participate in person for the whole course; and fluent in French (all our CPD courses were in French). Ethical approval was obtained from the Centre intégré universitaire de santé et de services sociaux de la Capitale-Nationale (CIUSSS-CN) Ethics Board (2017-2018-16 MP), the Hôpital Montfort Research ethics board (19-20-05-009), and the Vitalité Health Network research ethics board (CER-2019-18).

Intervention

Informed by a continuing medical education needs assessment by our key CPD stakeholder and partner, Médecins francophones du Canada (data not published), we chose patients with T2D and depression combined as the clinical topic, as physicians felt there was a gap in their education about this comorbidity. There is growing evidence of a link between T2D and depression and the importance of sex as a risk factor for this comorbidity (34-36). The team adapted an existing T2D and depression CPD course to include evidence-based sex and gender considerations. The original course, a 1-hour classroom-based activity, describes links between TD2 and depression, reviews CANMAT 2016 Depression Guidelines and reviews pharmacological and non-pharmacological treatment of TD2 and depression. We added sex- and gender-specific content including: 1) definitions and differences between the concepts of sex and gender, 2) epidemiological data on the differences in incidence, prevalence, morbidity and mortality between men and women with T2D and depression, and 3) a video explaining sex biases associated with these two conditions. The adapted CPD course (intervention) kept the original duration (one hour) and medical content of the original course (comparator). Links between T2D and depression were explained together with sex and gender differences, and reviews of pharmacological and non-pharmacological treatments were condensed. As per patient-partners' recommendations, we also held 30-minute semi-structured group discussions with both the intervention and control group immediately following the course. In the group discussion we presented a clinical case vignette on managing a patient with T2D and depression in which the health professional's behaviour exhibited various divergences with best clinical practices. We

asked participants to write down the main divergence and to categorize it within five categories determined by our team: 1) failure to mention positive factors for recovery, 2) failure to engage the patient in their health-related decision, 3) sex and gender biases, 4) failure to take into account notions of sex and gender, and 5) cannot be categorized. We prompted participants to discuss their perception of sex and gender considerations by linking them to the clinical vignette and to their clinical experience of integrating sex and gender considerations in general.

Depending on the setting (hospitals, family medicine groups, CME conferences) we either (1) assigned the participants to the control or intervention group on their arrival to achieve a balanced number of participants in both groups or (2) the participants registered in one group or the other, both groups being blinded to the intervention and control group. Efforts were made to equally divide groups regarding number and gender of participants. At registration, participants were told that it was a research project that required their consent. Participants could attend the course and receive CME credits whether they chose to participate in the study or not. All CPD courses were delivered by the same two physicians (one man, assigned to the control group, and one woman, assigned to the intervention group) in all the research settings. We planned to offer six courses (three intervention and three control), two in each province (control and intervention simultaneously). Each course (both control and intervention) was a 45-minute lecture on T2D and depression followed by 15 minutes to fill in the CPD-Reaction questionnaire. An additional 30 minutes was planned for the semi-structured group discussion.

Outcome Measures

We assessed three feasibility outcome measures: recruitment, retention and adherence: 1) recruitment of >90 course participants for six courses and study participation rate of >70% (28, 37), 2) retention of CPD organisations, collaborators and patient-partners throughout the project, 3) the holding of all planned CPD courses in all three provinces. Sample size was based on consultations with clinic managers and CPD providers and on practical considerations (e.g. average size of CPD courses, venues, the course being provided in French only).

We used CPD-Reaction (French version) to measure participants' behavioural intention to include sex and gender considerations in patient care. CPD-Reaction is a self-administered questionnaire (Cronbach α 0.79–0.89) (38, 39). Twelve items measure five constructs determined through a systematic review of theory-driven studies of behaviour change in health professionals: 1) behavioural intention, 2) beliefs about capabilities, 3) social influences, 4) beliefs about consequences, and 5) moral norm (37). The score for each construct is computed as the average of each item (Likert scale of 1 to 7), except for social influence, which is rated on a Likert scale of 1 to 5 (28). There is no global score. Finally, in group discussions, we identified barriers and facilitators to including sex and gender considerations in caring for patients with T2D and depression and mapped them onto the TDF. The TDF was developed through a consensus of experts who consolidated 33 psychosocial theories of behaviour change to generate 14 domains (40).

Data collection

Quantitative data were collected post-intervention with the CPD-Reaction questionnaire and sociodemographic questions (38). Semi-structured qualitative discussion took place in both intervention and control groups after the questionnaires were completed so as not to influence quantitative results. In both intervention and control groups, discussions were recorded and transcribed.

Analysis

Quantitative analysis

Categorical variables were described by reporting absolute (n) and relative (%) frequencies. Continuous variables were described by their measure of central tendency (mean and/or median) and dispersion (standard deviation and percentiles). Covariance analysis was used to compare the scores of the intervention and control groups. As the intention did not have a perfectly Gaussian distribution, we also compared intention scores using Wilcoxon's non-parametric analysis and used the Kruskal-Wallis test to compare medians. We used Spearman's rank test to assess the correlation between the intention scores and psychosocial factors (social influence, beliefs about capabilities, moral norms, beliefs about consequences). We used general linear models to assess

whether the intention score varied significantly from the control group to intervention group after adjusting for confounding factors. These factors were identified using the 10% change in the regression coefficient associated with the exposure variable (41, 42). However, to increase the appearance validity of the model, we constructed a separate model in which we forced age, gender and practice environment. SAS software (version 9.4) was used for all statistical analyses. The empirical significance threshold (P value) was set at 0.05 in bilateral analysis.

Qualitative analysis

The discussion transcripts were imported into N'Vivo V.12 for analysis. Using the TDF as a guide, two researchers reviewed and agreed on codes and data were simultaneously coded using a thematic deductive approach (ADT, AGo) (43). Data were then refined into TDF domains. As the discussion occurred in French, all illustrative quotes were translated into English by a master's student (ADT) and reviewed by a scientific translator. We calculated the frequency of each barrier and facilitator by recording the number of times it was mentioned in the four group discussions (GDs 1 to 4).

Triangulating quantitative and qualitative data

We triangulated quantitative and qualitative data to propose practical theory-driven recommendations for improving our CPD intervention (44). We compared the five psychosocial determinants measured in the CPD-Reaction questionnaire to the domains of the TDF. We observed where quantitative and qualitative data converged, where they offered additional information on the same constructs, and where they diverged. We derived recommendations using the COM-B model of behaviour (45). COM-B proposes three criteria essential for a behaviour to occur: capacity, opportunity and motivation (46). The subcategories of these criteria can be linked to the TDF domains and their associated barriers or facilitators. The COM-B also proposes nine intervention functions assigned to TDF domains that can prompt behaviour change: education, persuasion, incentivisation, coercion, training, restriction, environmental restructuring, modelling and enablement (31, 45, 47). Recommendations were made by identifying which of these intervention functions matched our results and then selecting relevant function-associated behaviour change techniques (45).

RESULTS

Recruitment and participant characteristics

We offered the 12 CPD courses (i.e. six intervention/control pairs) in each of three Canadian provinces: Quebec, Ontario and New Brunswick. Four pairs of courses were held in Quebec (two in Montreal, October 10th 2018 and October 30th 2019, and two in Quebec City, October 17th 2019 and January 29th 2019), one in Ontario (Ottawa, November 8th 2019) and one in New-Brunswick (Moncton, October 4th 2019).

Figure 1 illustrates the flow of participants. The participation rate (ratio of users who participated in the study to those who took the training) was 71% (127/178). Forty-nine of 92 questionnaires were analysed from the intervention groups and 78 of 86 from the control groups. Most participants were under 44 years old (n=80, 63%), women (n=101, 79.5%), practised in French (n=86, 67.7%), in Quebec (n=85, 66.9%) and in an urban setting (n=100, 78.8%) (**Table 1**).

Table 1: Sociodemographic characteristics of the participants in intervention and control groups

	TOTAL	**Intervention Group**	**Control Group**
No. of Participants	127	49	78
Age (years)*			
<44	80 (63.0)	28 (57.1)	52 (66.7)
≥ 45	42 (33.1)	19 (38.8)	23 (29.5)
Missing data	5 (3.9)	2 (4.1)	3 (3.8)
Gender*			
Women	101 (79.5)	40 (81.6)	61 (78.2)

Men	19 (15.0)	7 (14.3)	12 (15.4)
Missing data	7 (5.5)	2 (4.1)	5 (6.4)
Language of practice*			
French	86 (67.7)	32 (65.2)	54 (69.2)
Other	36 (28.3)	15 (30.6)	21 (26.9)
Missing data	5 (4.0)	2 (4.1)	3 (3.9)
Province of practice			
Quebec	85 (66.9)	31 (63.2)	54 (69.3)
Ontario	18 (14.2)	9 (18.4)	9 (11.5)
New Brunswick	16 (12.6)	7 (14.3)	9 (11.5)
Missing data	8 (6.3)	2 (4.1)	6 (7.7)
Practice environment*			
Urban	100 (78.8)	39 (79.6)	61 (78.2)
Rural	14 (11.0)	4 (8.2)	10 (12.8)
Missing data	13 (10.2)	6 (12.2)	7 (9.0)

*n(%)

Quantitative results

Feasibility

We recruited a total of 127 participants, a 41% increase from our target of 90 participants. Collaborators and executive committee members remained involved throughout the project. We held monthly executive committee meetings as planned. Our CPD trainings were held in the three provinces as planned. We gave 12 courses instead of the six initially planned, as additional organizations in Quebec City (n=1) and Montreal (n=2) showed

interest. Due to time constraints imposed by CME settings, completing 1.5 hours (45-min course, 15-min evaluation and 30-min discussion) in all settings was not possible, therefore we held the group discussions in only two out of the six settings (Montreal and Ottawa).

Behavioural Intention

The intervention aims to influence behaviour by modifying intention and its psychosocial determinants. For example, the intervention could change beliefs about capabilities (or confidence), by increasing health professionals' knowledge about the desired behavior. **Table 2** shows scores for intention and its psychosocial determinants for intervention and control groups as evaluated using the CPD-Reaction questionnaire. Mean difference between intervention and control scores for the four psychosocial determinants of behaviour change influencing intention were: MD=0.16 for social influence (95% CI: -0.26, 0.58), MD=0.63 for belief about capabilities (95% CI: 0.21, 1.06), MD=0.25 for moral norm (95% CI: -0.21, 0.72) and MD=0.22 for belief about consequences (95% CI: -0.23, 0.67). The mean intention score for including sex and gender considerations in patient care was higher in the intervention than in the control group, i.e. 5.65 (± 0.19) versus 5.19 (±0.15), on a scale from 1 (low) to 7 (high). The mean difference between the two groups was -0.47 (95% CI: -0.95, 0.01), with a p-value of 0.06 (**Supplementary table 1**). No statistically significant differences were observed for the remaining four psychosocial determinants. Bivariate analysis showed that the higher median for intention was significantly associated with age over 45 (p=0.03) and a rural practice environment (p=0.02) (**Supplementary table 1**). After adjusting for age, gender and practice environment, the mean difference in intention between the two groups was statistically significant: -0.57 (95% CI: -1.09, -0.05), with a p-value of 0.03 (**Table 3**).

Table 2: CPD-Reaction questionnaire mean scores

	Total	**Intervention**	**Control**	**Difference (95% CI)**
No. of participants	127	49	78	-
Psychosocial determinants – score range (1 to 7)*				

Social influence	4.62 (4.42; 4.83)	4.72 (4.44; 5,00)	4.56 (4.27; 4.85)	0.16 (-0.26; 0.58)
Beliefs about capabilities	5.1 (4.90; 5.33)	5.50 (5.27; 5.74)	4.87 (4.56; 5.17)	0.63 (0.21; 1.06)
Moral norm	5.90 (5.69; 6.13)	6.06 (5.80; 6.32)	5.81 (5.48; 6.14)	0.25 (-0.21; 0.72)
Beliefs about consequences	5.68 (5.46; 5.90)	5.82 (5.52; 6.11)	5.60 (5.28; 5.91)	0.22 (-0.23; 0.67)
Intention*	5.37 (5.13; 5.60)	5.65 (5.36; 5.95)	5.19 (4.85; 5.52)	0.47 (-0.01; 0.95)

*Mean (95% CI) ;

Table 3: Mean difference of the intention score between intervention and control groups

	Model 1*		**Model 2†**		**Model 3‡**	
	β (95% CI)	**P Value**	**β (95% CI)**	**P Value**	**β (95% IC)**	**P Value**
Control	Reference		Reference		Reference	
Intervention	-0.47 (-0.95;0.01)	**0.057**	-0.61 (-1.10;-0.12)	**0.015**	-0.57 (-1.09;-0.05)	**0.031**

95% CI, confidence interval at 95%;
*Non-adjusted;
†Adjusted for age and gender;
‡Adjusted for age, gender and environment of practice.

Qualitative findings

Due to time constraints imposed by CME settings, we held the group discussions in two out of the six settings, Montreal, October 30th 2019 and Ottawa, November 8th 2019. Thus four semi-structured group discussions (GD1, GD2, GD3, GD4) were conducted and 67 health professionals participated, reporting a variety of barriers and facilitators (**Table 4)**.

Table 4: Mapping facilitators and barriers to the Theoretical Domains Framework (TDF) with illustrative quotes and frequencies

TDF DOMAIN	FACILITATOR/ BARRIER	ILLUSTRATIVE QUOTES*	FREQUEN-CIES** (N=4 groups)
Skills	The health professional acknowledges different treatment methods by gender (Facilitator)	"Dominique, is that a man or a woman? … Because they are probably not treated the same" (GD4)	4
	The health professional acknowledges different clinical representation by gender (Facilitator)	"…I work as a nurse in cardiac and pulmonary rehabilitation, and … it is a fact, that women come less [to rehabilitation programs] in general than men. Women often will quit [rehabilitation] or they won't come because they're taking care of everyone. But something happens [illness] and then they don't have time to take care of themselves, because it's too much" (GD3)	1
	The health professional assumed the gender of the patient when analyzing a clinical vignette (Barrier)	"I assumed that it was a guy" (GD3) / "I presumed that it was a girl" (GD4)	3
Beliefs about Capabilities	The health professional feels he/she can accurately observe the phenotype of the patient (Facilitator)	"At the first contact we have with a patient … we see the phenotype there without talking about gender, it's one of the things that jumps out at you when you're taking notes." (GD3)	3
Social influences	The health professionals assume the patient's gender based on his/her societal role (Barrier)	"I heard 'civil servant', I don't know, in my head I was like 'civil servant', so it's a man." (GD4)	3
Knowledge	The health professional knows the differences between sex and gender in scientific literature (Facilitator)	"Yes, that's it actually, the biological aspect you certainly take into account in the study, but we are talking about the [social] categories of sex and gender… And menopause, and on the other hand [there's] also andropause" (GD2)	2
	The health professional did not	"Well, I don't know why we didn't note it	2

	ask the gender of the patient when analyzing a clinical vignette (Barrier)	[the gender of the patient], I don't have the answer to that. But … when we talk about the clinical context it is systemically noted in the first … sentence, in the first two words [of notes documenting a consultation]. It's hard to say that we ignore it [gender of the patient]. We didn't notice it here, but in clinical practice, have you ever met a patient without identifying their gender?" (GD3)	1
	The health professional is not aware of the concepts of sex and gender when analyzing a clinical vignette (Barrier)	"…but in the seminar, there was no emphasis on that, so it didn't jump out at us," (GD3)	
Beliefs about Consequences	The health professional mentions that they would not change their therapeutic approach according to the patient's gender (Barrier)	"I would say that I didn't see the need to know if it was a man or a woman…I never asked myself the question..." (GD1)	2
Environmental Context and Resources	The patient's sex is routinely recorded in medical notes (Facilitator)	"… in the clinical context it's [the sex of the patient] systematically noted in the first lines in every consultation. In the first sentence, in the first two words. It's hard to say that we ignore it." (GD3)	2
	The androcentric nature of the French language (the use of masculine generic language to refer to men and women, as well as other gender representation) (Barrier)	"In French everything is masculine until you know, like in the room here [mostly women participants] we'll say like "ils ont fait ça" [*ils* is a masculine pronoun] because you are the only men, but…" [generalizing to the masculine pronoun] (GD3) / "The language doesn't help … [to differentiate between men and women]." (GD3)	1
	The healthcare professional perceives that the language used by physicians towards a patient may be different according to sex and gender	"Well it's about when you say 'our diabetes' and 'your depression', if it had been a woman would we have said the same thing?… 'your depression' 'our diabetes'..." (GD2) [referring to the bias in the language to describe 'your' depression versus 'our' diabetes]	1

	(Barrier)		
Social/Professional Role and Identity	The health professional reflects positively on his/her relationship with the patient (Facilitator)	"I work in an exclusively white environment, and I am the only black person, and I have no problem whether [the patient] is male, female or a child" (GD3)	1
Intentions	The health professional has the intention to change his/her therapeutic approach by considering the differences of gender (Facilitator)	"With the information that I have here [clinical description of vignette], if I had 'menopaused woman', then I think I would have researched more, but with what I had here, I didn't [see the need]." (GD4)	1
	The health professional does not have the intention to change his/her therapeutic approach by considering the differences of gender (Barrier)	"With what I have here [descriptive information of the clinical vignette], I am not sure to what extent I would have changed my approach" (GD4)	1
Goals	The health professional does not perceive the integration of the concepts of sex and gender in clinical practice as a priority (Barrier)	"It wasn't important … the most important, [but] that doesn't mean that [the lack of sex and gender consideration in the clinical vignette] wasn't perceived" (GD4)	1
Memory, Attention and Decision Processes	The health professional does not consider that sex and gender are necessary parts of the decision-making process (Barrier)	"If it is not obvious, we are not inclined to do it… [take into consideration the sex and gender of the patient]" (GD2)	1

*Free translation from French
**The number of times that the barrier/facilitator appeared in the transcript

Barriers and facilitators mapped to the TDF domains

Ten barriers mapped to nine of the 14 TDF domains and seven facilitators mapped onto six of the domains. The most frequent barriers were related to Skills (e.g. failing to consider a patient's gender) (n=3) and to Social Influence (e.g. making gender assumptions about

employment) (n=3). The most frequent facilitators were also related to Skills (n=4) (**Table 4**).

We mapped to the Skills domain when the participants asked whether their patient was a woman or man before analyzing the clinical vignette, or else failed to ask the question (the fictive name of the patient – Dominique – was strategically ambiguous). Thus, failure to ask was coded as a barrier, and asking was coded as a facilitator. Discussion about information on sex and/or gender was coded as a facilitator in the Knowledge domain, but reporting differentiating between women and men patients in clinical practice was coded as a facilitator in the Skills domain. When participants reported not needing to know the patient's gender because this information would not have changed their intervention, we mapped the barrier to Beliefs about consequences domain. Participants documented some differences between men and women patients in their clinical practice, demonstrating ability acquired through practice to include sex and gender considerations. Participants also reported they did not ask the sex of the patient in the clinical vignette as they automatically observe a patient's sex in practice, so didn't feel the need to mention it in this context. This facilitator was mapped to the domain beliefs about capabilities (n=3). Some participants reported that they routinely observe and record a patient's sex when taking notes. This facilitator was mapped to the domain environmental context and resources, since it this is an institutional practice reflecting an organisational clinical culture, and could foster further awareness and consideration of sex and gender (**Table 4**).

Triangulation

CPD-Reaction psychosocial variables matched barriers that mapped onto to the TDF domains beliefs about consequences, social influence and intentions. CPD-Reaction psychosocial variables also matched facilitators that mapped onto to the TDF domains beliefs about capabilities and intentions. We identified six additional psychosocial variables from the TDF: knowledge, skills, goal, memory, attention and decision processes, environmental context and resources, social/professional role and identity. Results of triangulation were summarised with consequent recommendations (**Supplementary table 2)**. Recommendations for improving the CPD training were based on behaviour change techniques associated with the following functions: modelling, training, environmental

restructuring, enablement, education and goal settings (**Supplementary table 2)** (45). Training (n=5) and education (n=4) were the most frequent functions used in the recommendations.

DISCUSSION

We assessed the feasibility and impact of including sex and gender considerations in a CPD course on T2D and depression care on health professionals' intention to include sex and gender considerations in patient care. Recruited CPD organisations, collaborators and patient-partners stayed engaged throughout the study. All planned activities occurred and 71% of targeted health professionals participated. The intention to include sex and gender considerations in patient care was higher in the intervention group, and statistically significant when controlling for age, gender, and practice sites. Barriers were mostly related to skills and social influence and facilitators to skills and beliefs about capabilities. We triangulated results and produced recommendations for improving the CPD course. The following observations could enable CPD organisations to systematically improve CPD by integrating sex and gender considerations into their existing material.

First, all our predetermined feasibility criteria were met. In fact, due to increased interest in the topic, we recruited more participants and gave more CPD activities than planned. Recruitment may also have improved because we involved stakeholders early on in the research process, including in applying for the grant. Early engagement of stakeholders has been associated elsewhere with more successful recruitment (48). Therefore, elements that should be considered when designing similar CPD activities include, but are not limited to: 1) successful collaboration and co-creation with CPD organisations early on including during grant writing, 2) offering CME accreditation for the CPD activities, 3) the duration of the training, and 4) the evidence base relevant to the clinical topic (49).

Second, the CPD course that included sex and gender considerations increased health professionals' intention to include sex and gender considerations in patients' care. This may suggest a significant knowledge gap among participants. Studies show that health professionals lack knowledge of sex and gender differences in disease manifestation and outcomes and fail to recognize the gender constraints that their patients face (50-53). For example, in a cross-sectional survey of physicians (71% male), 55% said that the medical

curriculum did not adequately prepare them for dealing with sexual health problems, particularly those of female patients (50). In another study, only 49% of primary care physicians (n=200, 65% male) and 59% of cardiologists (n=100, 85% male) reported that their training prepared them to assess female patients' cardiovascular risk (52). Our study represents a promising avenue for rectifying these gaps. Furthermore, bivariate analyses of the between-group difference in the intention scores yielded significant results in older, but not younger, participants and in those practising in rural area. Their age and geographical isolation perhaps reduced their exposure to sex and gender issues, which have only been included in medical curricula since they qualified (53). They may also have less access to CPD training due to isolation, poor technological resources, low financial support (54, 55) and geographical variations in medical practice styles (56, 57). Future studies could further investigate the perceptions of health professionals in rural settings on age and gender. They could also document if patients experience geographical differences in care regarding sex and gender. Training could target older and rural health professionals, who seemed more open to modifying their clinical practice.

Third, beliefs about capabilities as a facilitator showed the strongest mean difference between the intervention and control groups. These results are consistent with a literature review of 277 studies showing that the mechanisms of action most frequently associated with behaviour change techniques are beliefs about capabilities and intention (58). Adding a practical component to the CPD course could strengthen beliefs about capabilities. Also, several barriers and facilitators to considering sex and gender in patient care were identified. Our qualitative analysis showed that participants did not consider integrating sex and gender into clinical practice as a priority, with social influences emerging as an important barrier. The social influence score as measured by CPD-Reaction also showed the lowest impact (MD=0.16), suggesting that the training did not address this factor (Table 2). A CPD course could offer a reflective segment on how social influence could be affecting their clinical practice (57, 59). Furthermore, belief about consequences had one of the lowest MD (0.22) of the five psychosocial determinants, and one associated barrier (n=2). This could be remedied by focusing more on the consequences of not integrating sex and gender into clinical practice (51).

Finally, in spite of the low priority given to sex and gender by our participants, qualitative analysis demonstrated that opportunities already exist for integrating these considerations into practice, such as the routine documenting of the patient's sex. CPD strategies could make more of these opportunities (60). For example, CPD activities could advocate for sex- and gender-equitable care when treating men and women for diabetes and depression. Indeed, specific attention could be given to diabetic foot care when treating men, while specific attention could be given to blood-glucose regulation and to family and lifestyle issues when treating women (7, 61).

This intervention could be adapted to medical fields other than T2D and depression, and to other countries and areas outside French-speaking provinces of Canada. While many of the barriers participants mentioned were culture- and language-specific to the Quebec or francophone context, many other languages (e.g. Spanish, German, Italian, and Portuguese) also generalise everything to the masculine gender, suggesting shared linguistic barriers. However, each culture has highly specific sex and gender norms affecting physicians' clinical assumptions (62). Our qualitative results highlight the fact that CPD on sex and gender considerations must be tailored to specific cultural contexts (17) and incorporate sex- and gender-based analysis tools (63).

Our study has a few limitations. As we used a single post-intervention measure, we cannot attribute the difference between the two groups solely to the intervention. However, our analysis suggests that those who completed the intervention increased their intention, as well as increasing all four psychosocial predictors, suggesting an association with the intervention. Second, the fact that participants could choose which course to attend (according to conference guidelines), and hence the non-randomized nature of the study, may have biased our feasibility findings. Also, the training was given by teachers of different genders for the intervention and control groups (a woman in the intervention group and a man in the control group). As a bias could have been introduced owing to differences in communication styles between men and women, the teaching teams practised the courses several times to ensure that teaching methods were equivalent. In addition, we ensured the teachers stayed with their respective groups for the six data collections. Also, due to ethics guidelines, we only analysed questionnaires completed by

participants who had also signed consent forms. Although the human resources for both groups were the same (trainer, research-assistant and patient-partners), the control group had an extra team member, resulting in unequal numbers of participants who signed consent in each group. The presence of this extra member could also explain the difference in the number of questionnaires collected in the two groups.

While there is evidence that intention is an effective determinant for measuring behaviour change (39), it is limited as a proxy. Finding other reliable measures of behaviour change is challenging (64). However, identifying barriers and facilitators to change is a first step (64). Semi-structured group discussions using a clinical vignette have also been shown to contribute to clinical behaviour change (64). Methods such as audit and feedback, as well as "commitment to change statements" could reduce the intention-behaviour gap and strengthen the understanding of clinical changes following CPD activities (65, 66).

Lastly, our discussion groups attracted many participants, limiting both participants' opportunity to speak and the depth of the discussion. Our mixed-methods approach is a strength of this study and our findings support the feasibility of a randomised trial informed by identified barriers and facilitators.

CONCLUSION

A CPD course with sex and gender considerations is feasible and well received by health professionals. The significant between-group difference in the intention scores suggests the intervention had a favorable impact on health professionals' intention to include sex and gender considerations when caring for their patients with T2D and depression. However, caution is required as this effect may be attributed to other sources given the non-randomised nature of our study. Future randomised controlled trials are needed to control for potential selection biases and confirm our results, accounting for barriers and facilitators in sex- and gender-adapted diabetes and depression care. Our findings will inform future CPD initiatives that address this and other inequities in health care pertaining to sex and gender.

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ADT, AGo, SGB, FL, NP and AB conceived and designed the study. ADT, AGo, SGB, DA, AGa, DRL, LV and FL participated to data collection. ADT, AGo, SGB, GN and FL participated to data analysis. All authors critically revised the interpretation of data. ADT, AGo, SGB and FL drafted the manuscript. All authors and members of the mATrICES-F Group read, provided feedback and approved the final manuscript.

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Disclaimer

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References

1. Clayton JA, Tannenbaum C. Reporting Sex, Gender, or Both in Clinical Research? JAMA. 2016;316(18):1863.
2. Institut de recherche en santé du Canada. Comment intégrer le sexe et le genre à la recherche 2019 [Available from: http://cihr-irsc.gc.ca/f/50836.html.
3. Johnson JL, Greaves L, Repta R. Better science with sex and gender: Facilitating the use of a sex and gender-based analysis in health research. International Journal for Equity in Health. 2009;8(1):14.
4. Oliffe J, Greaves L. Designing and Conducting Gender, Sex, and Health Research. Thousand Oaks, California2012. Available from: http://sk.sagepub.com/books/designing-and-conducting-gender-sex-and-health-research.
5. Légaré F, Lee-Gosselin H, Borduas F, Monette C, Bilodeau A, Tanguay D, et al. Approaches to considering sex and gender in continuous professional development for health and social care professionals: An emerging paradigm. Medical Teacher. 2018;40(9):875-9.
6. Tannenbaum C, Ellis RP, Eyssel F, Zou J, Schiebinger L. Sex and gender analysis improves science and engineering. Nature. 2019;575(7781):137-46.
7. Kautzky-Willer A, Harreiter J, Pacini G. Sex and Gender Differences in Risk, Pathophysiology and Complications of Type 2 Diabetes Mellitus. Endocrine Reviews. 2016;37(3):278-316.
8. Geary N. Counterpoint: physiologists should not distinguish "sex" and "gender". American Journal of Physiology-Regulatory, Integrative and Comparative Physiology. 2010;298(6):R1702-R4.

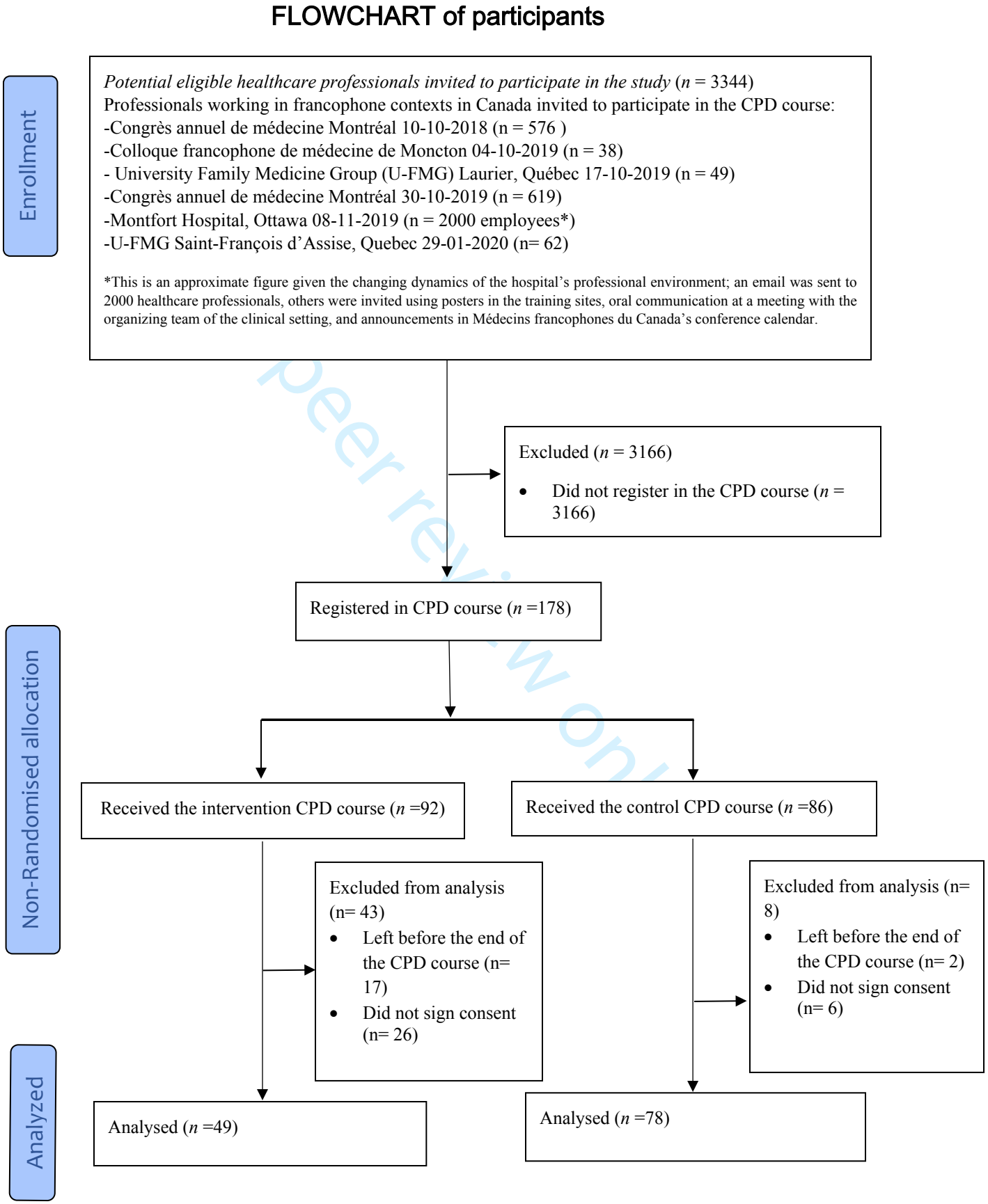
9. Demmer RT, Gelb S, Suglia SF, Keyes KM, Aiello AE, Colombo PC, et al. Sex Differences in the Association Between Depression, Anxiety, and Type 2 Diabetes Mellitus. 2015;77(4):467-77.
10. Kuehner C. Why is depression more common among women than among men? Lancet Psychiatry. 2017;4(2):146-58.
11. Turecki G, Brent DA. Suicide and suicidal behaviour. The Lancet. 2016;387(10024):1227-39.
12. Zhuang QS, Shen L, Ji HF. Quantitative assessment of the bidirectional relationships between diabetes and depression. Oncotarget. 2017;8(14):23389-400.
13. Ali S, Stone MA, Peters JL, Davies MJ, Khunti K. The prevalence of co-morbid depression in adults with Type 2 diabetes: a systematic review and meta-analysis. Diabetic Medicine. 2006;23(11):1165-73.
14. Ahmad A, Abujbara M, Jaddou H, Younes NA, Ajlouni K. Anxiety and Depression Among Adult Patients With Diabetic Foot: Prevalence and Associated Factors. Journal of clinical medicine research. 2018;10(5):411-8.
15. Toker S, Shirom A, Melamed S. Depression and the metabolic syndrome: gender-dependent associations. Depression and anxiety. 2008;25(8):661-9.
16. Möller-Leimkühler AM. Gender differences in cardiovascular disease and comorbid depression. Dialogues in clinical neuroscience. 2007;9(1):71-83.
17. Coen S BE. What a Difference Sex and Gender Make: A gender, Sex and Health Research Casebook. Vancouver; 2012.
18. Gilbert-Ouimet M, Trudel X, Aubé K, Ndjaboue R, Duchaine C, Blanchette C, et al. Differences between women and men in the relationship between psychosocial stressors at work and work absence due to mental health problem. Occupational and Environmental Medicine. 2020;77(9):603-10.
19. Deischinger C, Dervic E, Leutner M, Kosi-Trebotic L, Klimek P, Kautzky A, et al. Diabetes mellitus is associated with a higher risk for major depressive disorder in women than in men. BMJ Open Diabetes Research & Care. 2020;8(1):e001430.
20. Tannenbaum C, Greaves L, Graham ID. Why sex and gender matter in implementation research. BMC Medical Research Methodology. 2016;16(1).
21. Tannenbaum C, Clow B, Haworth-Brockman M, Voss P. Sex and gender considerations in Canadian clinical practice guidelines: a systematic review. CMAJ Open. 2017;5(1):E66-E73.
22. Ferlie EB, Shortell SM. Improving the quality of health care in the United Kingdom and the United States: a framework for change. Milbank Q. 2001;79(2):281-315.
23. Davis D, Evans M, Jadad A, Perrier L, Rath D, Ryan D, et al. The case for knowledge translation: shortening the journey from evidence to effect. Bmj. 2003;327(7405):33-5.
24. Davis D, Galbraith R. Continuing Medical Education Effect on Practice Performance. Chest. 2009;135(3):42S-8S.
25. Institute of Medicine. Redesigning Continuing Education in the Health Professions. Washington, DC: The National Academies Press; 2010. 296 p.
26. Godin G. Les comportements dans le domaine de la santé : Comprendre pour mieux intervenir. Montréal, Québec: Les Presses de l'Université de Montréal 2012.

27. Ajzen I. The theory of planned behavior. Organizational Behavior and Human Decision Processes. 1991;50(2):179-211.
28. Légaré F, Borduas, F., Freitas, A., Turcotte, S. User Manual – The Continuing Professional Development (CPD) Reaction Questionnaire. 2015.
29. Atkins L, Francis J, Islam R, O'Connor D, Patey A, Ivers N, et al. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. Implementation Science. 2017;12(1).
30. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. Implementation Science. 2012;7(1):37.
31. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. Implementation Science. 2011;6(1):42.
32. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355:i5239.
33. Gogovor A MT, Etherington N, Colantonio A, Légaré F, on behalf of the GIKT Group. Sex and gender analysis in knowledge translation interventions: challenges and solutions. Health Research Policy and Systems. 2020;18(1):108.
34. Atlantis E, Fahey P, Foster J. Collaborative care for comorbid depression and diabetes: a systematic review and meta-analysis. BMJ Open. 2014;4(4):e004706.
35. Holt RI, de Groot M, Golden SH. Diabetes and depression. Curr Diab Rep. 2014;14(6):491.
36. Harreiter J, Fadl H, Kautzky-Willer A, Simmons D. Do Women with Diabetes Need More Intensive Action for Cardiovascular Reduction than Men with Diabetes? Current diabetes reports. 2020;20(11):61.
37. Légaré F, Freitas A, Turcotte S, Borduas F, Jacques A, Luconi F, et al. Responsiveness of a simple tool for assessing change in behavioral intention after continuing professional development activities. PLOS ONE. 2017;12(5):e0176678.
38. Légaré F, Borduas F, Freitas A, Jacques A, Godin G, Luconi F, et al. Development of a Simple 12-Item Theory-Based Instrument to Assess the Impact of Continuing Professional Development on Clinical Behavioral Intentions. PLoS ONE. 2014;9(3):e91013.
39. Godin G, Bélanger-Gravel A, Eccles M, Grimshaw J. Healthcare professionals' intentions and behaviours: A systematic review of studies based on social cognitive theories. Implementation Science. 2008;3(1):36.
40. Michie S. Making psychological theory useful for implementing evidence based practice: a consensus approach. Quality and Safety in Health Care. 2005;14(1):26-33.
41. Mickey R M GS. The Impact of Confounder Selection Criteria on Effect Estimation American Journal of Epidemiology. 1989;129(1):125-37.
42. Budtz-Jørgensen E, Keiding N, Grandjean P, Weihe P. Confounder selection in environmental epidemiology: assessment of health effects of prenatal mercury exposure. Ann Epidemiol. 2007;17(1):27-35.
43. Atkins L, Francis J, Islam R, O'Connor D, Patey A, Ivers N, et al. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. Implement Sci. 2017;12(1):77.

44. O'Cathain A, Murphy E, Nicholl J. Three techniques for integrating data in mixed methods studies. Bmj. 2010;341:c4587.
45. Michie S, Atkins L, R. W. The behaviour change wheel : a guide to designing Interventions. Great Britain: Silverback Publishing; 2014.
46. West R, Michie S. A brief introduction to the COM-B Model of behaviour and the PRIME Theory of motivation. Qeios. 2020.
47. Agbadjé TT, Menear M, Dugas M, Gagnon M-P, Rahimi SA, Robitaille H, et al. Pregnant women's views on how to promote the use of a decision aid for Down syndrome prenatal screening: a theory-informed qualitative study. BMC Health Services Research. 2018;18(1).
48. Garvelink MM, Freitas A, Menear M, Brière N, Stacey D, Légaré F. In for a penny, in for a pound: the effect of pre-engaging healthcare organizations on their subsequent participation in trials. BMC Research Notes. 2015;8(1):751.
49. Little P, Hayes S. Continuing professional development (CPD): GPs' perceptions of post-graduate education-approved (PGEA) meetings and personal professional development plans (PDPs). 2003;20(2):192-8.
50. Veloshnee G, Loveday P-K. Gender biases and discrimination: a review of health care interpersonal interactions 2007 [Available from: https://www.who.int/social_determinants/resources/gender_biases_and_discrimination_wgkn_2007.pdf.
51. Mauvais-Jarvis F, Bairey Merz N, Barnes PJ, Brinton RD, Carrero J-J, Demeo DL, et al. Sex and gender: modifiers of health, disease, and medicine. The Lancet. 2020;396(10250):565-82.
52. Bairey Merz CN, Andersen H, Sprague E, Burns A, Keida M, Walsh MN, et al. Knowledge, Attitudes, and Beliefs Regarding Cardiovascular Disease in Women: The Women's Heart Alliance. J Am Coll Cardiol. 2017;70(2):123-32.
53. Kling JM, Rose SH, Kransdorf LN, Viggiano TR, Miller VM. Evaluation of sex- and gender-based medicine training in post-graduate medical education: a cross-sectional survey study. Biology of Sex Differences. 2016;7(S1).
54. Curran VR, Fleet L, Kirby F. Factors influencing rural health care professionals' access to continuing professional education. Aust J Rural Health. 2006;14(2):51-5.
55. Berndt A, Murray CM, Kennedy K, Stanley MJ, Gilbert-Hunt S. Effectiveness of distance learning strategies for continuing professional development (CPD) for rural allied health practitioners: a systematic review. BMC Medical Education. 2017;17(1).
56. OCDE. Geographic Variations in Health Care2014.
57. Bertakis KD, Helms LJ, Callahan EJ, Azari R, Robbins JA. The influence of gender on physician practice style. Med Care. 1995;33(4):407-16.
58. Carey RN, Connell LE, Johnston M, Rothman AJ, de Bruin M, Kelly MP, et al. Behavior Change Techniques and Their Mechanisms of Action: A Synthesis of Links Described in Published Intervention Literature. Annals of Behavioral Medicine. 2018;53(8):693-707.
59. Etherington N, Rodrigues IB, Giangregorio L, Graham ID, Hoens AM, Kasperavicius D, et al. Applying an intersectionality lens to the theoretical domains framework: a tool for thinking about how intersecting social identities and structures of power influence behaviour. BMC Medical Research Methodology. 2020;20(1).

60. Guly HR. Continuing professional development for doctors in accident and emergency. Journal of Accident & Emergency Medicine. 2000;17(1):12-4.
61. Peek ME. Gender differences in diabetes-related lower extremity amputations. Clinical orthopaedics and related research. 2011;469(7):1951-5.
62. Weziak-Bialowolska D. Differences in Gender Norms Between Countries: Are They Valid? The Issue of Measurement Invariance. European journal of population = Revue europeenne de demographie. 2015;31(1):51-76.
63. Macdermid JC, Graham ID. Knowledge Translation: Putting the "Practice" in Evidence-Based Practice. Hand Clinics. 2009;25(1):125-43.
64. Eccles MP, Hrisos S, Francis J, Kaner EF, Dickinson HO, Beyer F, et al. Do self-reported intentions predict clinicians' behaviour: a systematic review. Implementation Science. 2006;1(1).
65. Wakefield J, Herbert CP, Maclure M, Dormuth C, Wright JM, Legare J, et al. Commitment to change statements can predict actual change in practice. The Journal of continuing education in the health professions. 2003;23(2):81-93.
66. van Braak M, Visser M, Holtrop M, Statius Muller I, Bont J, van Dijk N. What motivates general practitioners to change practice behaviour? A qualitative study of audit and feedback group sessions in Dutch general practice. BMJ open. 2019;9(5):e025286.

Figure 1 Flowchart of participants



Supplementary table 1: Distribution of the scores of intention to include sex and gender considerations in patient care in the clinical context of T2D and depression

	Parametric estimation *				**Non-parametric estimation**†		
	Intervention	Control	Mean difference (95% CI)	*P*Value‡	Intervention	Control	*P* Value£
No. of participants	49	78			49	78	
Total	5.65±0.19	5.19±0.15	-0.47 (-0.95; 0.01)	0.057	5.50 (5.00; 6.50)	5.50 (4.50; .00)	0.162
Age (years)							
< 44	5.68±0.25	5.30±0.18	-0.38 (-1.00; 0.24)	0.226	5.50 (5.00; 6.50)	5.50 (5.00; 6.50)	0.717
≥ 45	5.92±0.29	4.93±0.26	-0.99 (-1.78; -0.20)	**0.016**	6.00 (5.00; 6.50)	5.50 (3.50; 6.00)	**0.029**
Gender							
Men	5.79±0.45	4.79±0.34	-0.99 (-2.19; 0.20)	0.098	6.00 (5.00; 6.50)	5.25 (3.50; 6.00)	0.070
Women	5.78±0.21	5.24±0.17	-0.54 (-1.08; 0.00)	0.051	5.50 (5.00; 6.50)	5.50 (4.50; 6.50)	0.245
Language							
French	5.81±0.20	5.35±0.16	-0.46 (-0.97; 0.05)	0.073	6.00 (5.00; 6.50)	5.50 (4.50; 6.00)	0.133
Other	5.70±0.42	4.76±0.35	-0.94 (-2.05; 0.17)	0.096	5.50 (5.00; 6.50)	5.50 (4.50; 6.00)	0.346
Province of practice							
Quebec	5.85±0.20	5.43±0.15	-0.43 (-0.94; 0.08)	0.097	6.00 (5.00; 6.50)	5.50 (5.00; 6.50)	0.144
Ontario	5.83±0.43	4.89±0.43	-0.94 (-2.23; 0.34)	0.138	6.00 (5.00; 6.50)	5.00 (4.50; 6.00)	0.223
New Brunswick	5.36±0.73	4.00±0.64	-1.36 (-3.44; 0.72)	0.184	5.50 (5.00; 5.50)	4.00 (1.00; 6.00)	0.512
Environment of practice							

Urban	5.74±0.20	5.37±0.16	-0.37 (-0.88; 0.13)	0.143	5.50 (5.00; 6.50)	5.50 (5.00; 6.50)	0.486
Rural	6.38±0.87	4.45±0.55	-1.93 (-4.17; 0.32)	0.086	6.25 (6.00; 6.75)	5.25 (3.50; 6.00)	**0.018**

*Mean±standard deviation;
†Median (25th percentile; 75th percentile);
‡Derived from the general linear models;
£Derived from the Kruskal-Wallis (Wilcoxon) test

Supplementary table 2: Recommendations for improving the CPD training, based on barriers and facilitators, using the COM-B model, the Theoretical Domains Framework and the CPD-Reaction questionnaire

COM-B criteria	COM-B criteria subcategory	TDF domains linked to COM-B	Barriers and facilitators perceived by health professionals to including sex and gender considerations in their clinical practice	Psychosocial determinants of the CPD-Reaction questionnaire	Recommendations (COM-B Intervention function)
Opportunity					
	Social	Social influence	Health professionals assume the patient's gender based on his/her societal role (Barrier)	Social influence	In the CPD course, a clinical case vignette could demonstrate the integration of sex and gender considerations and reflect on the different social stigmas associated with gender (Modelling)
	Physical	Environmental context and resources	The patient's sex is routinely recorded in medical notes (Facilitator)		CPD training could expand on routine practices that already include sex and gender in clinical practice, example: recording sex, but going further by asking questions about perceived gender, sexual orientation (Training)
			The androcentric nature of the French language (the use of masculine generic language to refer to men and women, as well as other gender representations) (Barrier)		CPD training could give prompts/cues to demonstrate sex- and gender-sensitive medical language (e.g. revised forms, gender sensitive formulation of questions on sexuality and relationships) to promote equity in clinical practice (Environmental restructuring) The CPD training could encourage health professionals to self-monitor their use of gender inclusive language (Training/Enablement)
			The healthcare professional perceives that the language used by physicians towards a patient may be		CPD training could demonstrate sex- and gender-sensitive behaviours and patterns of speech through video animations of clinical visits between health professionals and their

			different according to sex and gender (Barrier)		patients, as well as showing various health professional and patient scenarios (Training)
Motivation					
	Reflective	Social and professional role and identity	The health professional reflects positively on his/her relationship with the patient (Facilitator)		
		Beliefs about capabilities	The health professional feels he/she can accurately observe the phenotype of the patient (Facilitator)	Beliefs about capabilities	Self-monitoring of behaviour to encourage health professionals to analyse how they record patient phenotypes: what do they take into consideration? Do they ask specific questions or is it strictly observational? (Enablement)
		Intentions	The health professional has the intention to change his/her therapeutic approach by considering the differences of gender (Facilitator)	Intention	Enable health professionals to change their behaviour by demonstrating strategies they have already undertaken to consider the sex of the patient during their therapeutic approaches (Modelling)
			The health professional does not have the intention to change his/her therapeutic approach by considering the differences of gender (Barrier)		Offer information about social consequences of not modifying their care to include sex and gender considerations (Education) Offer information about health consequences of not modifying their care to include sex and gender considerations (Education)
		Goals	The health professional does not perceive the integration of the concepts of sex and gender in clinical practice as a priority (Barrier)		Enable participants to engage in action planning to include sex and gender considerations in their clinical practice, as well as implementation intentions (Enablement) Enable participants to engage in specific goal setting on how

					they would include sex and gender considerations in their clinical practice (Goal setting)
		Beliefs about consequences	The health professional mentions that they would not change their therapeutic approach according to the patient's gender (Barrier)	Beliefs about consequences	Offer CPD content with credible sources about the health consequences of not modifying their care to include sex and gender considerations (Education) Demonstration of various techniques, shared decision making, cues and prompts that include sex and gender considerations in care (Modelling)
Capability					
	Psychological	Memory, Attention and Decision Processes	The health professional perceives that sex and gender are not systematic in the decision-making process (Barrier)		Offer specific training to create routine and habit formation that encourages the systematic inclusion of sex and gender considerations in the decision-making process (Training)
		Cognitive and interpersonal skills	The health professional does not assume the sex of the patient and acknowledges different treatment methods by gender (Facilitator)		
			The health professional acknowledges different clinical representation by gender (Facilitator)		
			The health professional assumed the gender of the patient when analyzing a clinical vignette (Barrier)		As part of skills training, the CPD training could demonstrate how to explore the different aspects of sex attribution, without assuming the sex of the patient (Training) Give specific instructions on how to explore the different aspects of sex attribution,

					without assuming the sex of the patient (Training) Offer feedback on outcome(s) of assuming the sex of the patient in a clinical case vignette (Training) Offer a practice/rehearsal period after receiving instructions on how to explore the different aspects of sex attribution, without assuming the sex of the patient (Training)
		Knowledge	The health professional recognizes the differences between sex and gender in scientific literature (Facilitator)		
			The health professional did not ask the gender of the patient when analyzing a clinical vignette (Barrier)		Include information on the possible clinical outcome(s) of assuming the wrong sex or gender of the patient (Education)
			The health professional is not aware of the concepts of sex and gender (Barrier)		Offer information about health consequences of not considering or confusing sex and gender terms (Education)

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1 (mixed methods)
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	7-8
	2b	Specific objectives or research questions for pilot trial	8
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	8
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	9-10
	4b	Settings and locations where the data were collected	9-10
	4c	How participants were identified and consented	9-10
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9-10-11
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	11-12
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	NA
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	NA
Sample size	7a	Rationale for numbers in the pilot trial	11
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	NA
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	NA
Allocation concealment	9	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	NA

mechanism			
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	10-11
	11b	If relevant, description of the similarity of interventions	10-11
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	12-13
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	14
	13b	For each group, losses and exclusions after randomisation, together with reasons	14
Recruitment	14a	Dates defining the periods of recruitment and follow-up	14
	14b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	14-15
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	14-15-16
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	15-16-17
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
	19a	If relevant, other important unintended consequences	NA
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	24-25
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	24
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	22-23-24
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	23-24
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	5
Protocol	24	Where the pilot trial protocol can be accessed, if available	NA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	27
	26	Ethical approval or approval by research review committee, confirmed with reference number	27

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.
*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Integration of Sex and Gender in a Continuing Professional Development Course on Diabetes and Depression: A Mixed Methods Feasibility Study

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Integration of Sex and Gender in a Continuing Professional Development Course on Diabetes and Depression: A Mixed Methods Feasibility Study

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Abstract

Objectives Assess the feasibility and impact of a continuous professional development (CPD) course on type-2 diabetes and depression on health professionals' intention to include sex and gender considerations in patient care.

Design and setting In collaboration with CPD organisations and patient-partners, we conducted a mixed-methods feasibility controlled trial with post-intervention measures in three Canadian provinces.

Participants Of 178 eligible health professionals, 127 completed questionnaires and 67 participated in semi-structured group discussions.

Intervention and comparator An interactive one-hour CPD course, co-designed with patient-partners, on diabetes and depression with sex and gender considerations (innovation) was compared to a similar course without these considerations (comparator).

Outcomes Feasibility of recruitment and retention of CPD organisations and patient-partners throughout the study; adherence to planned activities; health professionals' intention to include sex and gender considerations in patient care as measured by the CPD-Reaction questionnaire; and barriers and facilitators using the Theoretical Domains Framework.

Results All recruited CPD organisations and patient-partners remained engaged throughout the study. All planned CPD courses occurred. Overall, 71% of eligible health professionals participated (63% under 44 years old; 79.5% women; 67.7% practising in French; 66.9% practising in Quebec; 78.8% in urban practice). After training, mean intention scores for the innovation (n=49) and control groups (n=78) were 5.65 ± 0.19 and 5.19 ± 0.15, respectively. Mean difference was -0.47 (CI -0.95 to 0.01; p=0.06). Adjusted for age, gender and practice settings, mean difference was -0.57 (CI -1.09 to -0.05; p=0.03). We identified eight Theoretical Domains related to barriers and six related to facilitators for providing sex- and gender-adapted diabetes and depression care.

Conclusions CPD training on diabetes and depression that includes sex and gender considerations is feasible and, compared to CPD training that does not, may prompt health

professionals to modify their care. Addressing identified barriers and facilitators could increase intention.

Registration number: NCT03928132 with ClinicalTrials.gov.

Keywords: Sex and gender, knowledge translation, continuous professional development, diabetes, depression, patient engagement, Theory of Planned Behaviour, Theoretical Domains, COM-B

Strengths and limitations of this study

- Continuous professional development (CPD) courses that included sex and gender considerations were co-designed with patients experiencing diabetes and/or depression.
- Outcome measures were informed by theory.
- This mixed-methods controlled trial used post-intervention measures only, as pre-intervention measures were not feasible. Although randomized allocation of participants was not possible, it was feasible to conduct a mixed-methods controlled trial.

INTRODUCTION

A variety of research initiatives are attempting to reduce health inequities between men and women (1, 2). Research that includes sex- and gender-based analysis results in more accurate evidence, more relevant recommendations, more specifically-targeted interventions, and better outcomes (3-6). Sex differences are biology-linked differences between females and males caused by different sex chromosomes, sex-specific gene expression of autosomes, sex hormones, and their effects on organ systems (7). Gender differences arise from sociocultural processes such as the different behaviours of women and men, their exposure to environmental influences, impacts of nutrition, lifestyles or stress, and attitudes towards illness, treatment and prevention (7). Gender roles and gender identity are influenced by a complex interplay between genetic, endocrinal, and social factors (8). Finally, sex and gender are not straightforward binary categories. Many femininities and masculinities exist and can influence other important sociodemographic variables (9).

During their lifetime women are twice as likely as men to be diagnosed with depression. In contrast, three times as many men commit suicide (5, 10, 11). Recent evidence supports a link between type 2 diabetes (T2D) and depression, and shows that sex and gender are influential factors in this comorbidity (7, 9). The prevalence of depression in diabetic patients is higher in females than males (23.8% and 12.8%, respectively) (7). On the other hand, a pooled result from 32 studies described that the risk of developing T2D in patients diagnosed with depression is higher in men than in women (RC=1.63 vs RC=1.29, respectively) (7, 12, 13). The differences are explained by biological differences and psychosocial factors such as body mass index, differences in the distribution of types of adipose tissue, an imbalance of sex hormones, socioeconomic status, psychosocial stress, and sleep deprivation (7, 9). Co-morbidity and mortality associated with the complications of T2D and depression are also different for men and women. For instance, men develop diabetic food syndrome at earlier ages and are more likely to have complications leading to amputations (7, 14). Women, on the other hand, have a higher risk of metabolic syndrome and fatal coronary heart disease than men (7, 15, 16). T2D and depression are also affected by gender differences. This gap could be explained in part by the different

behaviours associated gender representations of men and women, as well as their different perceptions of stress (17-19).

Despite the impacts of sex and gender differences on prevalence, diagnosis, treatment, outcomes, and equity, evidence on the importance of these differences has yet to be translated adequately into clinical training or practice (2, 5, 20). For example, a 2017 review suggested that only 35% of studies on Canadian practice guidelines, a cornerstone of knowledge translation, reported screening, diagnosis or management considerations specific to sex or gender, and only 25% used the terms "sex" and "gender" correctly (21).

Continuing professional development (CPD) is another cornerstone of knowledge translation as it mobilizes professional and regulatory bodies as well as educational institutions to foster changes in clinical practice (22, 23). We argue that integrating sex and gender considerations into CPD is a promising avenue for addressing the inequities between men and women (5). We define CPD as all educational activities serving to maintain or increase the knowledge, skills, work performance, and relationships that a clinician needs to serve patients, the public or the profession. (5, 24, 25). Courses should be informed by theory-based factors known to influence the adoption of a given behaviour. Although one of several other factors influencing behaviour change, such as organizational constraints, intention is considered an acceptable proxy. Indeed, according to Godin's integrated model for health professional behaviour change, behavioral intention is the central influencing factor on behaviour adoption. In turn, this intention is under the influence of a number of other socio-cognitive factors (26). We aimed to assess the feasibility and impact of including sex and gender considerations in a CPD course on T2D and depression on health professionals' intention to include sex and gender considerations in patient care.

METHODS

Study design and setting

We conducted a non-randomized mixed-methods study with a concurrent embedded design: (1) a two-arm non-randomized controlled trial with post-intervention measures only; and (2) semi-structured group discussions following the CPD course. We used the

Theory of Planned Behavior for quantitative analysis (27, 28), the Theoretical Domains Framework (TDF) for qualitative analysis (29, 30), and the COM-B (Capability, Opportunity, Motivation and Behavior) model to triangulate findings (31). We followed the CONSORT extension for Pilot and Feasibility Trials Checklist to report results (32).

This project is one of six that were funded by the Canadian Institutes of Health Research to explore sex and gender issues in knowledge translation (33), gender transformative approaches to knowledge translation, and sex- and gender-based analysis (5, 33).

A multidisciplinary team was created of 25 researchers: two sex and gender specialists, three patient-partners with experience with T2D and/or mental health issues (two men and one woman), two physicians, one nurse, two CPD managers, one research assistant and two trainees. An executive committee of 12 team members (including all patient-partners) held monthly meetings addressing the main concerns in each research phase. They chose the clinical topic of the course based on needs expressed by CPD providers (see Innovation below). They then adapted an existing diabetes and depression CPD course to include sex and gender considerations and contacted CPD providers in three Canadian provinces to collaborate on implementing the courses.

Patient involvement

Three patient-partners, core members of the executive committee, contributed to governance (e.g., attending meetings and courses, making executive decisions) and innovation design. They contributed their experience to the CPD course, helped collect data and interpret results, coauthored this paper and advised us on plain language use for our presentations.

Participants and recruitment

All health professionals working in the clinical settings where our CPD course was advertised, including hospitals and family medicine groups, or participating in the continuing medical education (CME) conference where the course was to be offered, were invited to participate. Invitations were by email and through the Internet registration platforms of CME conferences in three Canadian provinces (Quebec, Ontario, New-Brunswick). Participants stayed in their respective groups for the semi-structured group

discussion that immediately followed the CPD course. Inclusion criteria were: practising health professionals available to participate in person for the whole course; and fluent in French (all our CPD courses were in French). Ethical approval was obtained from the Centre intégré universitaire de santé et de services sociaux de la Capitale-Nationale (CIUSSS-CN) Ethics Board (2017-2018-16 MP), the Hôpital Montfort Research ethics board (19-20-05-009), and the Vitalité Health Network research ethics board (CER-2019-18).

Innovation

Informed by a continuing medical education needs assessment by our key CPD stakeholder and partner, Médecins francophones du Canada (data not published), we chose patients with T2D and depression combined as the clinical topic, as physicians felt there was a gap in their education about this comorbidity. There is growing evidence of a link between T2D and depression and the importance of sex as a risk factor for this comorbidity (34-36). The team adapted an existing T2D and depression CPD course to include evidence-based sex and gender considerations. The original course, a 1-hour classroom-based activity, describes links between T2D and depression, reviews CANMAT 2016 Depression Guidelines and reviews pharmacological and non-pharmacological treatment of T2D and depression. This original course was used in the control group. Participants in the innovation group attended the same course but adapted to integrate sex- and gender-specific content including: 1) definitions and differences between the concepts of sex and gender, 2) epidemiological data on the differences in incidence, prevalence, morbidity and mortality between men and women with T2D and depression, and 3) a video explaining sex biases associated with these two conditions. The adapted CPD course (innovation) kept the original duration (one hour) and medical content of the original course (comparator). Links between T2D and depression were explained together with sex and gender differences, and reviews of pharmacological and non-pharmacological treatments were condensed. As per patient-partners' recommendations, we also held 30-minute semi-structured group discussions with both the innovation and control group immediately following the course. In the group discussion we presented a clinical case vignette on managing a patient with T2D and

depression in which the health professional's behaviour exhibited various divergences with best clinical practices. We asked participants to write down the main divergence and to categorize it within five categories determined by our team: 1) failure to mention positive factors for recovery, 2) failure to engage the patient in their health-related decision, 3) sex and gender biases, 4) failure to take into account notions of sex and gender, and 5) cannot be categorized. We prompted participants to discuss their perception of sex and gender considerations by linking them to the clinical vignette and to their clinical experience of integrating sex and gender considerations in general.

Depending on the setting (hospitals, family medicine groups, CME conferences) we either (1) assigned the participants to the control or innovation group on their arrival to achieve a balanced number of participants in both groups or (2) the participants registered in one group or the other, both groups being blinded to the innovation and control group. Thus participants entered the classroom for whichever course they signed up for. There was no communication between these groups, as the two courses were given simultaneously. Participants had all received the same invitation to attend a course on T2D and depression. There was no mention of sex and gender content before participants entered the room. Efforts were made to equally divide groups regarding number and gender of participants. At registration, participants were told that it was a research project that required their consent. Participants could attend the course and receive CME credits whether they chose to participate in the study or not. All CPD courses were delivered by the same two physicians (one man, assigned to the control group, and one woman, assigned to the innovation group) in all the research settings. We planned to offer six courses (three innovation and three control), two in each province (control and innovation simultaneously). Each course (both control and innovation) was a 45-minute lecture on T2D and depression followed by 15 minutes to fill in the CPD-Reaction questionnaire. An additional 30 minutes was planned for the semi-structured group discussion.

Outcome Measures

We assessed three feasibility outcome measures: recruitment, retention and adherence: 1) recruitment of >90 course participants for six courses and study participation rate of >70% (28, 37), 2) retention of CPD organisations, collaborators and patient-partners

throughout the project, 3) the holding of all planned CPD courses in all three provinces. Sample size was based on consultations with clinic managers and CPD providers and on practical considerations (e.g. average size of CPD courses, venues, the course being provided in French only).

We used CPD-Reaction (French version) to measure participants' behavioural intention to include sex and gender considerations in patient care. CPD-Reaction is a self-administered questionnaire (Cronbach α 0.79–0.89) (38, 39). Twelve items measure five constructs determined through a systematic review of theory-driven studies of behaviour change in health professionals: 1) behavioural intention, 2) beliefs about capabilities, 3) social influences, 4) beliefs about consequences, and 5) moral norm (37). The score for each construct is computed as the average of each item (Likert scale of 1 to 7), except for social influence, which is rated on a Likert scale of 1 to 5 (28). There is no global score. Finally, in group discussions, we identified barriers and facilitators to including sex and gender considerations in caring for patients with T2D and depression and mapped them onto the TDF. The TDF was developed through a consensus of experts who consolidated 33 psychosocial theories of behaviour change to generate 14 domains (40).

Data collection

Quantitative data were collected post-intervention with the CPD-Reaction questionnaire and sociodemographic questions (38). Semi-structured qualitative discussion took place in both innovation and control groups after the questionnaires were completed so as not to influence quantitative results. In both innovation and control groups, discussions were recorded and transcribed.

Analysis

Quantitative analysis

Categorical variables were described by reporting absolute (n) and relative (%) frequencies. Continuous variables were described by their measure of central tendency (mean and/or median) and dispersion (standard deviation and percentiles). Covariance analysis was used to compare the scores of the innovation and control groups. As the intention did not have a perfectly Gaussian distribution, we also compared intention

scores using Wilcoxon's non-parametric analysis and used the Kruskal-Wallis test to compare medians. We used Spearman's rank test to assess the correlation between the intention scores and psychosocial factors (social influence, beliefs about capabilities, moral norms, beliefs about consequences). We used general linear models to assess whether the intention score varied significantly from the control group to innovation group after adjusting for confounding factors. These factors were identified using the 10% change in the regression coefficient associated with the exposure variable (41, 42). However, to increase the appearance validity of the model, we constructed a separate model in which we forced age, gender and practice environment. SAS software (version 9.4) was used for all statistical analyses. The empirical significance threshold (P value) was set at 0.05 in bilateral analysis.

Qualitative analysis

The discussion transcripts were imported into N'Vivo V.12 for analysis. Using the TDF as a guide, two researchers reviewed and agreed on codes and data were simultaneously coded using a thematic deductive approach (ADT, AGo) (43). Data were then refined into TDF domains. As the discussion occurred in French, all illustrative quotes were translated into English by a master's student (ADT) and reviewed by a scientific translator. We calculated the frequency of each barrier and facilitator by recording the number of times it was mentioned in the four group discussions (GDs 1 to 4).

Triangulating quantitative and qualitative data

We triangulated quantitative and qualitative data to propose practical theory-driven recommendations for improving our CPD innovation (44). We compared the five psychosocial determinants measured in the CPD-Reaction questionnaire to the domains of the TDF. We observed where quantitative and qualitative data converged, where they offered additional information on the same constructs, and where they diverged. We derived recommendations using the COM-B model of behaviour (45). COM-B proposes three criteria essential for a behaviour to occur: capacity, opportunity and motivation (46). The subcategories of these criteria can be linked to the TDF domains and their associated barriers or facilitators. The COM-B also proposes nine intervention functions assigned to TDF domains that can prompt behaviour change: education, persuasion, incentivisation,

coercion, training, restriction, environmental restructuring, modelling and enablement (31, 45, 47). Recommendations were made by identifying which of these intervention functions matched our results and then selecting relevant function-associated behaviour change techniques (45).

RESULTS

Recruitment and participant characteristics

We offered the 12 CPD courses (i.e. six innovation/control pairs) in each of three Canadian provinces: Quebec, Ontario and New Brunswick. Four pairs of courses were held in Quebec (two in Montreal, October 10th 2018 and October 30th 2019, and two in Quebec City, October 17th 2019 and January 29th 2019), one in Ontario (Ottawa, November 8th 2019) and one in New-Brunswick (Moncton, October 4th 2019).

Figure 1 illustrates the flow of participants. The participation rate (ratio of users who participated in the study to those who took the training) was 71% (127/178). Forty-nine of 92 questionnaires were analysed from the innovation groups and 78 of 86 from the control groups. Most participants were under 44 years old (n=80, 63%), women (n=101, 79.5%), practised in French (n=86, 67.7%), in Quebec (n=85, 66.9%) and in an urban setting (n=100, 78.8%) (**Table 1**).

Table 1: Sociodemographic characteristics of the participants in innovation and control groups

	TOTAL	**Innovation Group**	**Control Group**
No. of Participants	127	49	78
Age (years)*			
<44	80 (63.0)	28 (57.1)	52 (66.7)
≥ 45	42 (33.1)	19 (38.8)	23 (29.5)
Missing data	5 (3.9)	2 (4.1)	3 (3.8)

Gender*			
Women	101 (79.5)	40 (81.6)	61 (78.2)
Men	19 (15.0)	7 (14.3)	12 (15.4)
Missing data	7 (5.5)	2 (4.1)	5 (6.4)
Language of practice*			
French	86 (67.7)	32 (65.2)	54 (69.2)
Other	36 (28.3)	15 (30.6)	21 (26.9)
Missing data	5 (4.0)	2 (4.1)	3 (3.9)
Province of practice			
Quebec	85 (66.9)	31 (63.2)	54 (69.3)
Ontario	18 (14.2)	9 (18.4)	9 (11.5)
New Brunswick	16 (12.6)	7 (14.3)	9 (11.5)
Missing data	8 (6.3)	2 (4.1)	6 (7.7)
Practice environment*			
Urban	100 (78.8)	39 (79.6)	61 (78.2)
Rural	14 (11.0)	4 (8.2)	10 (12.8)
Missing data	13 (10.2)	6 (12.2)	7 (9.0)

*n(%)

Quantitative results

Feasibility

We recruited a total of 127 participants, a 41% increase from our target of 90 participants. Collaborators and executive committee members remained involved throughout the project. We held monthly executive committee meetings as planned. Our CPD trainings

were held in the three provinces as planned. We gave 12 courses instead of the six initially planned, as additional organizations in Quebec City (n=1) and Montreal (n=2) showed interest. Due to time constraints imposed by CME settings, completing 1.5 hours (45-min course, 15-min evaluation and 30-min discussion) in all settings was not possible, therefore we held the group discussions in only two out of the six settings (Montreal and Ottawa).

Behavioural Intention

The innovation aims to influence behaviour by modifying intention and its psychosocial determinants. For example, the innovation could change beliefs about capabilities (or confidence), by increasing health professionals' knowledge about the desired behavior. **Table 2** shows scores for intention and its psychosocial determinants for innovation and control groups as evaluated using the CPD-Reaction questionnaire. Mean difference between innovation and control scores for the four psychosocial determinants of behaviour change influencing intention were: MD=0.16 for social influence (95% CI: -0.26, 0.58), MD=0.63 for belief about capabilities (95% CI: 0.21, 1.06), MD=0.25 for moral norm (95% CI: -0.21, 0.72) and MD=0.22 for belief about consequences (95% CI: -0.23, 0.67). The mean intention score for including sex and gender considerations in patient care was higher in the innovation than in the control group, i.e. 5.65 (± 0.19) versus 5.19 (±0.15), on a scale from 1 (low) to 7 (high). The mean difference between the two groups was -0.47 (95% CI: -0.95, 0.01), with a p-value of 0.06 (**Supplementary table 1**). No statistically significant differences were observed for the remaining four psychosocial determinants. Bivariate analysis showed that the higher median for intention was significantly associated with age over 45 (p=0.03) and a rural practice environment (p=0.02) (**Supplementary table 1**). After adjusting for age, gender and practice environment, the mean difference in intention between the two groups was statistically significant: -0.57 (95% CI: -1.09, -0.05), with a p-value of 0.03 (**Table 3**).

Table 2: CPD-Reaction questionnaire mean scores

	Total	**Innovation**	**Control**	**Difference (95% CI)**
No. of participants	127	49	78	-

Psychosocial determinants – score range (1 to 7)*				
Social influence	4.62 (4.42; 4.83)	4.72 (4.44; 5,00)	4.56 (4.27; 4.85)	0.16 (-0.26; 0.58)
Beliefs about capabilities	5.1 (4.90; 5.33)	5.50 (5.27; 5.74)	4.87 (4.56; 5.17)	0.63 (0.21; 1.06)
Moral norm	5.90 (5.69; 6.13)	6.06 (5.80; 6.32)	5.81 (5.48; 6.14)	0.25 (-0.21; 0.72)
Beliefs about consequences	5.68 (5.46; 5.90)	5.82 (5.52; 6.11)	5.60 (5.28; 5.91)	0.22 (-0.23; 0.67)
Intention*	5.37 (5.13; 5.60)	5.65 (5.36; 5.95)	5.19 (4.85; 5.52)	0.47 (-0.01; 0.95)

*Mean (95% CI) ;

Table 3: Mean difference of the intention score between innovation and control groups

	Model 1*		**Model 2†**		**Model 3‡**	
	β (95% CI)	**P Value**	**β (95% CI)**	**P Value**	**β (95% IC)**	**P Value**
Control	Reference		Reference		Reference	
Innovation	-0.47 (-0.95;0.01)	**0.057**	-0.61 (-1.10;-0.12)	**0.015**	-0.57 (-1.09;-0.05)	**0.031**

95% CI, confidence interval at 95%;
*Non-adjusted;
†Adjusted for age and gender;
‡Adjusted for age, gender and environment of practice.

Qualitative findings

Due to time constraints imposed by CME settings, we held the group discussions in two out of the six settings, Montreal, October 30th 2019 and Ottawa, November 8th 2019. Thus

four semi-structured group discussions (GD1, GD2, GD3, GD4) were conducted and 67 health professionals participated, reporting a variety of barriers and facilitators (**Table 4)**.

Table 4: Mapping facilitators and barriers to the Theoretical Domains Framework (TDF) with illustrative quotes and frequencies

TDF DOMAIN	FACILITATOR/ BARRIER	ILLUSTRATIVE QUOTES*	FREQUEN-CIES** (N=4 groups)
Skills	The health professional acknowledges different treatment methods by gender (Facilitator)	"Dominique, is that a man or a woman? … Because they are probably not treated the same" (GD4)	4
	The health professional acknowledges different clinical representation by gender (Facilitator)	"…I work as a nurse in cardiac and pulmonary rehabilitation, and … it is a fact, that women come less [to rehabilitation programs] in general than men. Women often will quit [rehabilitation] or they won't come because they're taking care of everyone. But something happens [illness] and then they don't have time to take care of themselves, because it's too much" (GD3)	1
	The health professional assumed the gender of the patient when analyzing a clinical vignette (Barrier)	"I assumed that it was a guy" (GD3) / "I presumed that it was a girl" (GD4)	3
Beliefs about Capabilities	The health professional feels he/she can accurately observe the phenotype of the patient (Facilitator)	"At the first contact we have with a patient … we see the phenotype there without talking about gender, it's one of the things that jumps out at you when you're taking notes." (GD3)	3
Social influences	The health professionals assume the patient's gender based on his/her societal role (Barrier)	"I heard 'civil servant', I don't know, in my head I was like 'civil servant', so it's a man." (GD4)	3
Knowledge	The health professional knows the differences between sex and gender in scientific	"Yes, that's it actually, the biological aspect you certainly take into account in the study, but we are talking about the [social] categories of sex and gender… And	2

	literature (Facilitator)	menopause, and on the other hand [there's] also andropause" (GD2)	
	The health professional did not ask the gender of the patient when analyzing a clinical vignette (Barrier)	"Well, I don't know why we didn't note it [the gender of the patient], I don't have the answer to that. But … when we talk about the clinical context it is systemically noted in the first … sentence, in the first two words [of notes documenting a consultation]. It's hard to say that we ignore it [gender of the patient]. We didn't notice it here, but in clinical practice, have you ever met a patient without identifying their gender?" (GD3)	2 1
	The health professional is not aware of the concepts of sex and gender when analyzing a clinical vignette (Barrier)	"…but in the seminar, there was no emphasis on that, so it didn't jump out at us," (GD3)	
Beliefs about Consequences	The health professional mentions that they would not change their therapeutic approach according to the patient's gender (Barrier)	"I would say that I didn't see the need to know if it was a man or a woman…I never asked myself the question..." (GD1)	2
Environmental Context and Resources	The patient's sex is routinely recorded in medical notes (Facilitator)	"… in the clinical context it's [the sex of the patient] systematically noted in the first lines in every consultation. In the first sentence, in the first two words. It's hard to say that we ignore it." (GD3)	2
	The androcentric nature of the French language (the use of masculine generic language to refer to men and women, as well as other gender representation) (Barrier)	"In French everything is masculine until you know, like in the room here [mostly women participants] we'll say like "ils ont fait ça" [*ils* is a masculine pronoun] because you are the only men, but…" [generalizing to the masculine pronoun] (GD3) / "The language doesn't help … [to differentiate between men and women]." (GD3)	1
	The healthcare professional perceives that the language used by	"Well it's about when you say 'our diabetes' and 'your depression', if it had been a woman would we have said the same thing?… 'your depression' 'our diabetes'..." (GD2)	1

	physicians towards a patient may be different according to sex and gender (Barrier)	[referring to the bias in the language to describe 'your' depression versus 'our' diabetes]	
Social/Professional Role and Identity	The health professional reflects positively on his/her relationship with the patient (Facilitator)	"I work in an exclusively white environment, and I am the only black person, and I have no problem whether [the patient] is male, female or a child" (GD3)	1
Intentions	The health professional has the intention to change his/her therapeutic approach by considering the differences of gender (Facilitator)	"With the information that I have here [clinical description of vignette], if I had 'menopaused woman', then I think I would have researched more, but with what I had here, I didn't [see the need]." (GD4)	1
	The health professional does not have the intention to change his/her therapeutic approach by considering the differences of gender (Barrier)	"With what I have here [descriptive information of the clinical vignette], I am not sure to what extent I would have changed my approach" (GD4)	1
Goals	The health professional does not perceive the integration of the concepts of sex and gender in clinical practice as a priority (Barrier)	"It wasn't important … the most important, [but] that doesn't mean that [the lack of sex and gender consideration in the clinical vignette] wasn't perceived" (GD4)	1
Memory, Attention and Decision Processes	The health professional does not consider that sex and gender are necessary parts of the decision-making process (Barrier)	"If it is not obvious, we are not inclined to do it… [take into consideration the sex and gender of the patient]" (GD2)	1

*Free translation from French

**The number of times that the barrier/facilitator appeared in the transcript

Barriers and facilitators mapped to the TDF domains

Ten barriers mapped to nine of the 14 TDF domains and seven facilitators mapped onto six of the domains. The most frequent barriers were related to Skills (e.g. failing to consider a

patient's gender) (n=3) and to Social Influence (e.g. making gender assumptions about employment) (n=3). The most frequent facilitators were also related to Skills (n=4) (**Table 4**).

We mapped to the Skills domain when the participants asked whether their patient was a woman or man before analyzing the clinical vignette, or else failed to ask the question (the fictive name of the patient – Dominique – was strategically ambiguous). Thus, failure to ask was coded as a barrier, and asking was coded as a facilitator. Discussion about information on sex and/or gender was coded as a facilitator in the Knowledge domain, but reporting differentiating between women and men patients in clinical practice was coded as a facilitator in the Skills domain. When participants reported not needing to know the patient's gender because this information would not have changed their intervention, we mapped the barrier to Beliefs about consequences domain. Participants documented some differences between men and women patients in their clinical practice, demonstrating ability acquired through practice to include sex and gender considerations. Participants also reported they did not ask the sex of the patient in the clinical vignette as they automatically observe a patient's sex in practice, so didn't feel the need to mention it in this context. This facilitator was mapped to the domain beliefs about capabilities (n=3). Some participants reported that they routinely observe and record a patient's sex when taking notes. This facilitator was mapped to the domain environmental context and resources, since it this is an institutional practice reflecting an organisational clinical culture, and could foster further awareness and consideration of sex and gender (**Table 4**).

Triangulation

CPD-Reaction psychosocial variables matched barriers that mapped onto to the TDF domains beliefs about consequences, social influence and intentions. CPD-Reaction psychosocial variables also matched facilitators that mapped onto to the TDF domains beliefs about capabilities and intentions. We identified six additional psychosocial variables from the TDF: knowledge, skills, goal, memory, attention and decision processes, environmental context and resources, social/professional role and identity. Results of triangulation were summarised with consequent recommendations (**Supplementary table 2)**. Recommendations for improving the CPD training were based on behaviour change

techniques associated with the following functions: modelling, training, environmental restructuring, enablement, education and goal settings (**Supplementary table 2)** (45). Training (n=5) and education (n=4) were the most frequent functions used in the recommendations.

DISCUSSION

We assessed the feasibility and impact of including sex and gender considerations in a CPD course on T2D and depression care on health professionals' intention to include sex and gender considerations in patient care. Recruited CPD organisations, collaborators and patient-partners stayed engaged throughout the study. All planned activities occurred and 71% of targeted health professionals participated. The intention to include sex and gender considerations in patient care was higher in the innovation group, and statistically significant when controlling for age, gender, and practice sites. Barriers were mostly related to skills and social influence and facilitators to skills and beliefs about capabilities. We triangulated results and produced recommendations for improving the CPD course. The following observations could enable CPD organisations to systematically improve CPD by integrating sex and gender considerations into their existing material.

First, all our predetermined feasibility criteria were met. In fact, due to increased interest in the topic, we recruited more participants and gave more CPD activities than planned. Recruitment may also have improved because we involved stakeholders early on in the research process, including in applying for the grant. Early engagement of stakeholders has been associated elsewhere with more successful recruitment (48). Therefore, elements that should be considered when designing similar CPD activities include, but are not limited to: 1) successful collaboration and co-creation with CPD organisations early on including during grant writing, 2) offering CME accreditation for the CPD activities, 3) the duration of the training, and 4) the evidence base relevant to the clinical topic (49).

Second, the CPD course that included sex and gender considerations increased health professionals' intention to include sex and gender considerations in patients' care. This may suggest a significant knowledge gap among participants. Studies show that health professionals lack knowledge of sex and gender differences in disease manifestation and outcomes and fail to recognize the gender constraints that their patients face (50-53). For

example, in a cross-sectional survey of physicians (71% male), 55% said that the medical curriculum did not adequately prepare them for dealing with sexual health problems, particularly those of female patients (50). In another study, only 49% of primary care physicians (n=200, 65% male) and 59% of cardiologists (n=100, 85% male) reported that their training prepared them to assess female patients' cardiovascular risk (52). Our study represents a promising avenue for rectifying these gaps. Furthermore, bivariate analyses of the between-group difference in the intention scores yielded significant results in older, but not younger, participants and in those practising in rural area. Their age and geographical isolation perhaps reduced their exposure to sex and gender issues, which have only been included in medical curricula since they qualified (53). They may also have less access to CPD training due to isolation, poor technological resources, low financial support (54, 55) and geographical variations in medical practice styles (56, 57). Future studies could further investigate the perceptions of health professionals in rural settings on age and gender. They could also document if patients experience geographical differences in care regarding sex and gender. Training could target older and rural health professionals, who seemed more open to modifying their clinical practice.

Third, beliefs about capabilities as a facilitator showed the strongest mean difference between the innovation and control groups. These results are consistent with a literature review of 277 studies showing that the mechanisms of action most frequently associated with behaviour change techniques are beliefs about capabilities and intention (58). Adding a practical component to the CPD course could strengthen beliefs about capabilities. Also, several barriers and facilitators to considering sex and gender in patient care were identified. Our qualitative analysis showed that participants did not consider integrating sex and gender into clinical practice as a priority, with social influences emerging as an important barrier. The social influence score as measured by CPD-Reaction also showed the lowest impact (MD=0.16), suggesting that the training did not address this factor (Table 2). A CPD course could offer a reflective segment on how social influence could be affecting their clinical practice (57, 59). Furthermore, belief about consequences had one of the lowest MD (0.22) of the five psychosocial determinants, and one associated barrier (n=2). This could be remedied by focusing more on the consequences of not integrating sex and gender into clinical practice (51).

Finally, in spite of the low priority given to sex and gender by our participants, qualitative analysis demonstrated that opportunities already exist for integrating these considerations into practice, such as the routine documenting of the patient's sex. CPD strategies could make more of these opportunities (60). For example, CPD activities could advocate for sex- and gender-equitable care when treating men and women for diabetes and depression. Indeed, specific attention could be given to diabetic foot care when treating men, while specific attention could be given to blood-glucose regulation and to family and lifestyle issues when treating women (7, 61).

This innovation could be adapted to medical fields other than T2D and depression, and to other countries and areas outside French-speaking provinces of Canada. While many of the barriers participants mentioned were culture- and language-specific to the Quebec or francophone context, many other languages (e.g. Spanish, German, Italian, and Portuguese) also generalise everything to the masculine gender, suggesting shared linguistic barriers. However, each culture has highly specific sex and gender norms affecting physicians' clinical assumptions (62). Our qualitative results highlight the fact that CPD on sex and gender considerations must be tailored to specific cultural contexts (17) and incorporate sex- and gender-based analysis tools (63).

Our study has a few limitations. As we used a single post-intervention measure, we cannot attribute the difference between the two groups solely to the innovation. However, our analysis suggests that those who completed the innovation increased their intention, as well as increasing all four psychosocial predictors, suggesting an association with the innovation. Second, the fact that participants could choose which course to attend (according to conference guidelines), and hence the non-randomized nature of the study, may have biased our feasibility findings. Also, the training was given by teachers of different genders for the innovation and control groups (a woman in the innovation group and a man in the control group). As a bias could have been introduced owing to differences in communication styles between men and women, the teaching teams practised the courses several times to ensure that teaching methods were equivalent. In addition, we ensured the teachers stayed with their respective groups for the six data collections. Also, due to ethics guidelines, we only analysed questionnaires completed by participants who had also signed

consent forms. Although the human resources for both groups were the same (trainer, research-assistant and patient-partners), the control group had an extra team member, resulting in unequal numbers of participants who signed consent in each group. The presence of this extra member could also explain the difference in the number of questionnaires collected in the two groups.

While there is evidence that intention is an effective determinant for measuring behaviour change (39), it is limited as a proxy. Finding other reliable measures of behaviour change is challenging (64). However, identifying barriers and facilitators to change is a first step (64). Semi-structured group discussions using a clinical vignette have also been shown to contribute to clinical behaviour change (64). Methods such as audit and feedback, as well as "commitment to change statements" could reduce the intention-behaviour gap and strengthen the understanding of clinical changes following CPD activities (65, 66).

Lastly, our discussion groups attracted many participants, limiting both participants' opportunity to speak and the depth of the discussion. Our mixed-methods approach is a strength of this study and our findings support the feasibility of a randomised trial informed by identified barriers and facilitators.

CONCLUSION

A CPD course with sex and gender considerations is feasible and well received by health professionals. The significant between-group difference in the intention scores suggests the innovation had a favorable impact on health professionals' intention to include sex and gender considerations when caring for their patients with T2D and depression. However, caution is required as this effect may be attributed to other sources given the non-randomised nature of our study. Future randomised controlled trials are needed to control for potential selection biases and confirm our results, accounting for barriers and facilitators in sex- and gender-adapted diabetes and depression care. Our findings will inform future CPD initiatives that address this and other inequities in health care pertaining to sex and gender.

Figure Legend

Figure 1: Flowchart of participants

*This is an approximate figure given the changing dynamics of the hospital's professional environment; an email was sent to 2000 employees including healthcare professionals, others were invited using posters in the training sites, oral communication at a meeting with the organizing team of the clinical setting, and announcements in Médecins francophones du Canada's conference calendar.

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ADT, AGo, SGB, FL, NP and AB conceived and designed the study. ADT, AGo, SGB, DA, AGa, DRL, LV and FL participated to data collection. ADT, AGo, SGB, GN and FL participated to data analysis. All authors critically revised the interpretation of data. ADT, AGo, SGB and FL drafted the manuscript. All authors and members of the mATrICES-F Group read, provided feedback and approved the final manuscript.

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Disclaimer

The findings and views are those of the authors.

Competing interests

None declared.

Patient consent for publication

Not applicable.

Ethics approval

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Not required.

Data sharing statement

Data are available upon reasonable request.

References

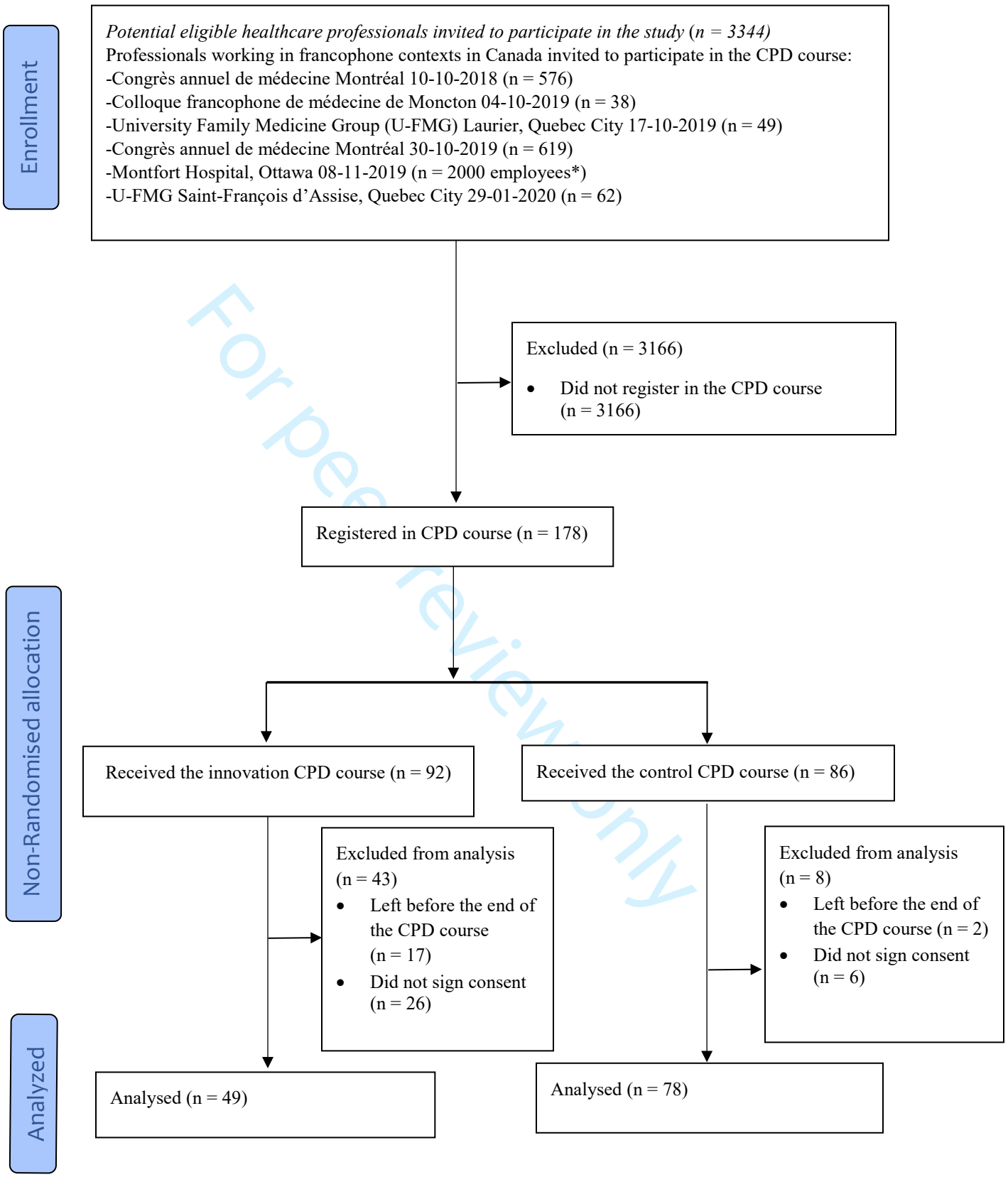
1. Clayton JA, Tannenbaum C. Reporting Sex, Gender, or Both in Clinical Research? JAMA. 2016;316(18):1863.
2. Institut de recherche en santé du Canada. Comment intégrer le sexe et le genre à la recherche 2019 [Available from: http://cihr-irsc.gc.ca/f/50836.html.
3. Johnson JL, Greaves L, Repta R. Better science with sex and gender: Facilitating the use of a sex and gender-based analysis in health research. International Journal for Equity in Health. 2009;8(1):14.
4. Oliffe J, Greaves L. Designing and Conducting Gender, Sex, and Health Research. Thousand Oaks, California2012. Available from: http://sk.sagepub.com/books/designing-and-conducting-gender-sex-and-health-research.
5. Légaré F, Lee-Gosselin H, Borduas F, Monette C, Bilodeau A, Tanguay D, et al. Approaches to considering sex and gender in continuous professional development for health and social care professionals: An emerging paradigm. Medical Teacher. 2018;40(9):875-9.
6. Tannenbaum C, Ellis RP, Eyssel F, Zou J, Schiebinger L. Sex and gender analysis improves science and engineering. Nature. 2019;575(7781):137-46.
7. Kautzky-Willer A, Harreiter J, Pacini G. Sex and Gender Differences in Risk, Pathophysiology and Complications of Type 2 Diabetes Mellitus. Endocrine Reviews. 2016;37(3):278-316.
8. Geary N. Counterpoint: physiologists should not distinguish "sex" and "gender". American Journal of Physiology-Regulatory, Integrative and Comparative Physiology. 2010;298(6):R1702-R4.

9. Demmer RT, Gelb S, Suglia SF, Keyes KM, Aiello AE, Colombo PC, et al. Sex Differences in the Association Between Depression, Anxiety, and Type 2 Diabetes Mellitus. 2015;77(4):467-77.
10. Kuehner C. Why is depression more common among women than among men? Lancet Psychiatry. 2017;4(2):146-58.
11. Turecki G, Brent DA. Suicide and suicidal behaviour. The Lancet. 2016;387(10024):1227-39.
12. Zhuang QS, Shen L, Ji HF. Quantitative assessment of the bidirectional relationships between diabetes and depression. Oncotarget. 2017;8(14):23389-400.
13. Ali S, Stone MA, Peters JL, Davies MJ, Khunti K. The prevalence of co-morbid depression in adults with Type 2 diabetes: a systematic review and meta-analysis. Diabetic Medicine. 2006;23(11):1165-73.
14. Ahmad A, Abujbara M, Jaddou H, Younes NA, Ajlouni K. Anxiety and Depression Among Adult Patients With Diabetic Foot: Prevalence and Associated Factors. Journal of clinical medicine research. 2018;10(5):411-8.
15. Toker S, Shirom A, Melamed S. Depression and the metabolic syndrome: gender-dependent associations. Depression and anxiety. 2008;25(8):661-9.
16. Möller-Leimkühler AM. Gender differences in cardiovascular disease and comorbid depression. Dialogues in clinical neuroscience. 2007;9(1):71-83.
17. Coen S BE. What a Difference Sex and Gender Make: A gender, Sex and Health Research Casebook. Vancouver; 2012.
18. Gilbert-Ouimet M, Trudel X, Aubé K, Ndjaboue R, Duchaine C, Blanchette C, et al. Differences between women and men in the relationship between psychosocial stressors at work and work absence due to mental health problem. Occupational and Environmental Medicine. 2020;77(9):603-10.
19. Deischinger C, Dervic E, Leutner M, Kosi-Trebotic L, Klimek P, Kautzky A, et al. Diabetes mellitus is associated with a higher risk for major depressive disorder in women than in men. BMJ Open Diabetes Research & Care. 2020;8(1):e001430.
20. Tannenbaum C, Greaves L, Graham ID. Why sex and gender matter in implementation research. BMC Medical Research Methodology. 2016;16(1).
21. Tannenbaum C, Clow B, Haworth-Brockman M, Voss P. Sex and gender considerations in Canadian clinical practice guidelines: a systematic review. CMAJ Open. 2017;5(1):E66-E73.
22. Ferlie EB, Shortell SM. Improving the quality of health care in the United Kingdom and the United States: a framework for change. Milbank Q. 2001;79(2):281-315.
23. Davis D, Evans M, Jadad A, Perrier L, Rath D, Ryan D, et al. The case for knowledge translation: shortening the journey from evidence to effect. Bmj. 2003;327(7405):33-5.
24. Davis D, Galbraith R. Continuing Medical Education Effect on Practice Performance. Chest. 2009;135(3):42S-8S.
25. Institute of Medicine. Redesigning Continuing Education in the Health Professions. Washington, DC: The National Academies Press; 2010. 296 p.
26. Godin G. Les comportements dans le domaine de la santé : Comprendre pour mieux intervenir. Montréal, Québec: Les Presses de l'Université de Montréal 2012.

27. Ajzen I. The theory of planned behavior. Organizational Behavior and Human Decision Processes. 1991;50(2):179-211.
28. Légaré F, Borduas, F., Freitas, A., Turcotte, S. User Manual – The Continuing Professional Development (CPD) Reaction Questionnaire. 2015.
29. Atkins L, Francis J, Islam R, O'Connor D, Patey A, Ivers N, et al. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. Implementation Science. 2017;12(1).
30. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. Implementation Science. 2012;7(1):37.
31. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. Implementation Science. 2011;6(1):42.
32. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355:i5239.
33. Gogovor A MT, Etherington N, Colantonio A, Légaré F, on behalf of the GIKT Group. Sex and gender analysis in knowledge translation interventions: challenges and solutions. Health Research Policy and Systems. 2020;18(1):108.
34. Atlantis E, Fahey P, Foster J. Collaborative care for comorbid depression and diabetes: a systematic review and meta-analysis. BMJ Open. 2014;4(4):e004706.
35. Holt RI, de Groot M, Golden SH. Diabetes and depression. Curr Diab Rep. 2014;14(6):491.
36. Harreiter J, Fadl H, Kautzky-Willer A, Simmons D. Do Women with Diabetes Need More Intensive Action for Cardiovascular Reduction than Men with Diabetes? Current diabetes reports. 2020;20(11):61.
37. Légaré F, Freitas A, Turcotte S, Borduas F, Jacques A, Luconi F, et al. Responsiveness of a simple tool for assessing change in behavioral intention after continuing professional development activities. PLOS ONE. 2017;12(5):e0176678.
38. Légaré F, Borduas F, Freitas A, Jacques A, Godin G, Luconi F, et al. Development of a Simple 12-Item Theory-Based Instrument to Assess the Impact of Continuing Professional Development on Clinical Behavioral Intentions. PLoS ONE. 2014;9(3):e91013.
39. Godin G, Bélanger-Gravel A, Eccles M, Grimshaw J. Healthcare professionals' intentions and behaviours: A systematic review of studies based on social cognitive theories. Implementation Science. 2008;3(1):36.
40. Michie S. Making psychological theory useful for implementing evidence based practice: a consensus approach. Quality and Safety in Health Care. 2005;14(1):26-33.
41. Mickey R M GS. The Impact of Confounder Selection Criteria on Effect Estimation American Journal of Epidemiology. 1989;129(1):125-37.
42. Budtz-Jørgensen E, Keiding N, Grandjean P, Weihe P. Confounder selection in environmental epidemiology: assessment of health effects of prenatal mercury exposure. Ann Epidemiol. 2007;17(1):27-35.
43. Atkins L, Francis J, Islam R, O'Connor D, Patey A, Ivers N, et al. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. Implement Sci. 2017;12(1):77.

44. O'Cathain A, Murphy E, Nicholl J. Three techniques for integrating data in mixed methods studies. Bmj. 2010;341:c4587.
45. Michie S, Atkins L, R. W. The behaviour change wheel : a guide to designing Interventions. Great Britain: Silverback Publishing; 2014.
46. West R, Michie S. A brief introduction to the COM-B Model of behaviour and the PRIME Theory of motivation. Qeios. 2020.
47. Agbadjé TT, Menear M, Dugas M, Gagnon M-P, Rahimi SA, Robitaille H, et al. Pregnant women's views on how to promote the use of a decision aid for Down syndrome prenatal screening: a theory-informed qualitative study. BMC Health Services Research. 2018;18(1).
48. Garvelink MM, Freitas A, Menear M, Brière N, Stacey D, Légaré F. In for a penny, in for a pound: the effect of pre-engaging healthcare organizations on their subsequent participation in trials. BMC Research Notes. 2015;8(1):751.
49. Little P, Hayes S. Continuing professional development (CPD): GPs' perceptions of post-graduate education-approved (PGEA) meetings and personal professional development plans (PDPs). 2003;20(2):192-8.
50. Veloshnee G, Loveday P-K. Gender biases and discrimination: a review of health care interpersonal interactions 2007 [Available from: https://www.who.int/social_determinants/resources/gender_biases_and_discrimination_wgkn_2007.pdf.
51. Mauvais-Jarvis F, Bairey Merz N, Barnes PJ, Brinton RD, Carrero J-J, Demeo DL, et al. Sex and gender: modifiers of health, disease, and medicine. The Lancet. 2020;396(10250):565-82.
52. Bairey Merz CN, Andersen H, Sprague E, Burns A, Keida M, Walsh MN, et al. Knowledge, Attitudes, and Beliefs Regarding Cardiovascular Disease in Women: The Women's Heart Alliance. J Am Coll Cardiol. 2017;70(2):123-32.
53. Kling JM, Rose SH, Kransdorf LN, Viggiano TR, Miller VM. Evaluation of sex- and gender-based medicine training in post-graduate medical education: a cross-sectional survey study. Biology of Sex Differences. 2016;7(S1).
54. Curran VR, Fleet L, Kirby F. Factors influencing rural health care professionals' access to continuing professional education. Aust J Rural Health. 2006;14(2):51-5.
55. Berndt A, Murray CM, Kennedy K, Stanley MJ, Gilbert-Hunt S. Effectiveness of distance learning strategies for continuing professional development (CPD) for rural allied health practitioners: a systematic review. BMC Medical Education. 2017;17(1).
56. OCDE. Geographic Variations in Health Care2014.
57. Bertakis KD, Helms LJ, Callahan EJ, Azari R, Robbins JA. The influence of gender on physician practice style. Med Care. 1995;33(4):407-16.
58. Carey RN, Connell LE, Johnston M, Rothman AJ, de Bruin M, Kelly MP, et al. Behavior Change Techniques and Their Mechanisms of Action: A Synthesis of Links Described in Published Intervention Literature. Annals of Behavioral Medicine. 2018;53(8):693-707.
59. Etherington N, Rodrigues IB, Giangregorio L, Graham ID, Hoens AM, Kasperavicius D, et al. Applying an intersectionality lens to the theoretical domains framework: a tool for thinking about how intersecting social identities and structures of power influence behaviour. BMC Medical Research Methodology. 2020;20(1).

60. Guly HR. Continuing professional development for doctors in accident and emergency. Journal of Accident & Emergency Medicine. 2000;17(1):12-4.
61. Peek ME. Gender differences in diabetes-related lower extremity amputations. Clinical orthopaedics and related research. 2011;469(7):1951-5.
62. Weziak-Bialowolska D. Differences in Gender Norms Between Countries: Are They Valid? The Issue of Measurement Invariance. European journal of population = Revue europeenne de demographie. 2015;31(1):51-76.
63. Macdermid JC, Graham ID. Knowledge Translation: Putting the "Practice" in Evidence-Based Practice. Hand Clinics. 2009;25(1):125-43.
64. Eccles MP, Hrisos S, Francis J, Kaner EF, Dickinson HO, Beyer F, et al. Do self-reported intentions predict clinicians' behaviour: a systematic review. Implementation Science. 2006;1(1).
65. Wakefield J, Herbert CP, Maclure M, Dormuth C, Wright JM, Legare J, et al. Commitment to change statements can predict actual change in practice. The Journal of continuing education in the health professions. 2003;23(2):81-93.
66. van Braak M, Visser M, Holtrop M, Statius Muller I, Bont J, van Dijk N. What motivates general practitioners to change practice behaviour? A qualitative study of audit and feedback group sessions in Dutch general practice. BMJ open. 2019;9(5):e025286.



Supplementary table 1: Distribution of the scores of intention to include sex and gender considerations in patient care in the clinical context of T2D and depression

	Parametric estimation*				**Non-parametric estimation†**		
	Innovation	Control	Mean difference (95% CI)	*P*Value‡	Innovation	Control	*P* Value£
No. of participants	49	78			49	78	
Total	5.65±0.19	5.19±0.15	-0.47 (-0.95; 0.01)	0.057	5.50 (5.00; 6.50)	5.50 (4.50; .00)	0.162
Age (years)							
< 44	5.68±0.25	5.30±0.18	-0.38 (-1.00; 0.24)	0.226	5.50 (5.00; 6.50)	5.50 (5.00; 6.50)	0.717
≥ 45	5.92±0.29	4.93±0.26	-0.99 (-1.78; -0.20)	**0.016**	6.00 (5.00; 6.50)	5.50 (3.50; 6.00)	**0.029**
Gender							
Men	5.79±0.45	4.79±0.34	-0.99 (-2.19; 0.20)	0.098	6.00 (5.00; 6.50)	5.25 (3.50; 6.00)	0.070
Women	5.78±0.21	5.24±0.17	-0.54 (-1.08; 0.00)	0.051	5.50 (5.00; 6.50)	5.50 (4.50; 6.50)	0.245
Language							
French	5.81±0.20	5.35±0.16	-0.46 (-0.97; 0.05)	0.073	6.00 (5.00; 6.50)	5.50 (4.50; 6.00)	0.133
Other	5.70±0.42	4.76±0.35	-0.94 (-2.05; 0.17)	0.096	5.50 (5.00; 6.50)	5.50 (4.50; 6.00)	0.346
Province of practice							
Quebec	5.85±0.20	5.43±0.15	-0.43 (-0.94; 0.08)	0.097	6.00 (5.00; 6.50)	5.50 (5.00; 6.50)	0.144
Ontario	5.83±0.43	4.89±0.43	-0.94 (-2.23; 0.34)	0.138	6.00 (5.00; 6.50)	5.00 (4.50; 6.00)	0.223
New Brunswick	5.36±0.73	4.00±0.64	-1.36 (-3.44; 0.72)	0.184	5.50 (5.00; 5.50)	4.00 (1.00; 6.00)	0.512
Environment of practice							

Urban	5.74±0.20	5.37±0.16	-0.37 (-0.88; 0.13)	0.143	5.50 (5.00; 6.50)	5.50 (5.00; 6.50)	0.486
Rural	6.38±0.87	4.45±0.55	-1.93 (-4.17; 0.32)	0.086	6.25 (6.00; 6.75)	5.25 (3.50; 6.00)	**0.018**

*Mean±standard deviation;
†Median (25th percentile; 75th percentile);
‡Derived from the general linear models;
£Derived from the Kruskal-Wallis (Wilcoxon) test

Supplementary table 2: Recommendations for improving the CPD training, based on barriers and facilitators, using the COM-B model, the Theoretical Domains Framework and the CPD-Reaction questionnaire

COM-B criteria	COM-B criteria subcategory	TDF domains linked to COM-B	Barriers and facilitators perceived by health professionals to including sex and gender considerations in their clinical practice	Psychosocial determinants of the CPD-Reaction questionnaire	Recommendations (COM-B Intervention function)
Opportunity					
	Social	Social influence	Health professionals assume the patient's gender based on his/her societal role (Barrier)	Social influence	In the CPD course, a clinical case vignette could demonstrate the integration of sex and gender considerations and reflect on the different social stigmas associated with gender (Modelling)
	Physical	Environmental context and resources	The patient's sex is routinely recorded in medical notes (Facilitator)		CPD training could expand on routine practices that already include sex and gender in clinical practice, example: recording sex, but going further by asking questions about perceived gender, sexual orientation (Training)
			The androcentric nature of the French language (the use of masculine generic language to refer to men and women, as well as other gender representations) (Barrier)		CPD training could give prompts/cues to demonstrate sex- and gender-sensitive medical language (e.g. revised forms, gender sensitive formulation of questions on sexuality and relationships) to promote equity in clinical practice (Environmental restructuring) The CPD training could encourage health professionals to self-monitor their use of gender inclusive language (Training/Enablement)
			The healthcare professional perceives that the language used by physicians towards a patient may be		CPD training could demonstrate sex- and gender-sensitive behaviours and patterns of speech through video animations of clinical visits between health professionals and their

			different according to sex and gender (Barrier)		patients, as well as showing various health professional and patient scenarios (Training)
Motivation					
	Reflective	Social and professional role and identity	The health professional reflects positively on his/her relationship with the patient (Facilitator)		
		Beliefs about capabilities	The health professional feels he/she can accurately observe the phenotype of the patient (Facilitator)	Beliefs about capabilities	Self-monitoring of behaviour to encourage health professionals to analyse how they record patient phenotypes: what do they take into consideration? Do they ask specific questions or is it strictly observational? (Enablement)
		Intentions	The health professional has the intention to change his/her therapeutic approach by considering the differences of gender (Facilitator)	Intention	Enable health professionals to change their behaviour by demonstrating strategies they have already undertaken to consider the sex of the patient during their therapeutic approaches (Modelling)
			The health professional does not have the intention to change his/her therapeutic approach by considering the differences of gender (Barrier)		Offer information about social consequences of not modifying their care to include sex and gender considerations (Education) Offer information about health consequences of not modifying their care to include sex and gender considerations (Education)
		Goals	The health professional does not perceive the integration of the concepts of sex and gender in clinical practice as a priority (Barrier)		Enable participants to engage in action planning to include sex and gender considerations in their clinical practice, as well as implementation intentions (Enablement) Enable participants to engage in specific goal setting on how

					they would include sex and gender considerations in their clinical practice (Goal setting)
		Beliefs about consequences	The health professional mentions that they would not change their therapeutic approach according to the patient's gender (Barrier)	Beliefs about consequences	Offer CPD content with credible sources about the health consequences of not modifying their care to include sex and gender considerations (Education) Demonstration of various techniques, shared decision making, cues and prompts that include sex and gender considerations in care (Modelling)
Capability					
	Psychological	Memory, Attention and Decision Processes	The health professional perceives that sex and gender are not systematic in the decision-making process (Barrier)		Offer specific training to create routine and habit formation that encourages the systematic inclusion of sex and gender considerations in the decision-making process (Training)
		Cognitive and interpersonal skills	The health professional does not assume the sex of the patient and acknowledges different treatment methods by gender (Facilitator)		
			The health professional acknowledges different clinical representation by gender (Facilitator)		
			The health professional assumed the gender of the patient when analyzing a clinical vignette (Barrier)		As part of skills training, the CPD training could demonstrate how to explore the different aspects of sex attribution, without assuming the sex of the patient (Training) Give specific instructions on how to explore the different aspects of sex attribution,

					without assuming the sex of the patient (Training) Offer feedback on outcome(s) of assuming the sex of the patient in a clinical case vignette (Training) Offer a practice/rehearsal period after receiving instructions on how to explore the different aspects of sex attribution, without assuming the sex of the patient (Training)
		Knowledge	The health professional recognizes the differences between sex and gender in scientific literature (Facilitator)		
			The health professional did not ask the gender of the patient when analyzing a clinical vignette (Barrier)		Include information on the possible clinical outcome(s) of assuming the wrong sex or gender of the patient (Education)
			The health professional is not aware of the concepts of sex and gender (Barrier)		Offer information about health consequences of not considering or confusing sex and gender terms (Education)

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1 (mixed methods)
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	7-8
	2b	Specific objectives or research questions for pilot trial	8
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	8
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	9-10
	4b	Settings and locations where the data were collected	9-10
	4c	How participants were identified and consented	9-10
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9-10-11
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	11-12
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	NA
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	NA
Sample size	7a	Rationale for numbers in the pilot trial	11
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	NA
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	NA
Allocation concealment	9	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	NA

mechanism			
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	10-11
	11b	If relevant, description of the similarity of interventions	10-11
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	12-13
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	14
	13b	For each group, losses and exclusions after randomisation, together with reasons	14
Recruitment	14a	Dates defining the periods of recruitment and follow-up	14
	14b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	14-15
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	14-15-16
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	15-16-17
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
	19a	If relevant, other important unintended consequences	NA
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	24-25
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	24
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	22-23-24
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	23-24
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	5
Protocol	24	Where the pilot trial protocol can be accessed, if available	NA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	27
	26	Ethical approval or approval by research review committee, confirmed with reference number	27

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*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Integration of Sex and Gender in a Continuing Professional Development Course on Diabetes and Depression: A Mixed Methods Feasibility Study

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Integration of Sex and Gender in a Continuing Professional Development Course on Diabetes and Depression: A Mixed Methods Feasibility Study

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Abstract

Objectives Assess the feasibility and impact of a continuous professional development (CPD) course on type-2 diabetes and depression on health professionals' intention to include sex and gender considerations in patient care.

Design and setting In collaboration with CPD organisations and patient-partners, we conducted a mixed-methods feasibility controlled trial with post-intervention measures in three Canadian provinces.

Participants Of 178 eligible health professionals, 127 completed questionnaires and 67 participated in semi-structured group discussions.

Intervention and comparator An interactive one-hour CPD course, co-designed with patient-partners, on diabetes and depression that included sex and gender considerations (innovation) was compared to a similar course that didn't include them (comparator).

Outcomes Feasibility of recruitment and retention of CPD organisations and patient-partners throughout the study; adherence to planned activities; health professionals' intention to include sex and gender considerations in patient care as measured by the CPD-Reaction questionnaire; and barriers and facilitators using the Theoretical Domains Framework.

Results All recruited CPD organisations and patient-partners remained engaged throughout the study. All planned CPD courses occurred. Overall, 71% of eligible health professionals participated (63% under 44 years old; 79.5% women; 67.7% practising in French; 66.9% practising in Quebec; 78.8% in urban practice). After training, mean intention scores for the innovation (n=49) and control groups (n=78) were 5.65 ± 0.19 and 5.19 ± 0.15, respectively. Mean difference was -0.47 (CI -0.95 to 0.01; p=0.06). Adjusted for age, gender and practice settings, mean difference was -0.57 (CI -1.09 to -0.05; p=0.03). We identified eight Theoretical Domains related to barriers and six related to facilitators for providing sex- and gender-adapted diabetes and depression care.

Conclusions CPD training on diabetes and depression that includes sex and gender considerations is feasible and, compared to CPD training that does not, may prompt health

professionals to modify their care. Addressing identified barriers and facilitators could increase intention.

Registration number: NCT03928132 with ClinicalTrials.gov.

Keywords: Sex and gender, knowledge translation, continuous professional development, diabetes, depression, patient engagement, Theory of Planned Behaviour, Theoretical Domains, COM-B

Strengths and limitations of this study

- Continuous professional development (CPD) courses that included sex and gender considerations were co-designed with patients experiencing diabetes and/or depression.
- Outcome measures were informed by theory.
- This mixed-methods controlled trial used post-intervention measures only, as pre-intervention measures were not feasible. Although randomised allocation of participants was not possible, it was feasible to conduct a mixed-methods controlled trial.

INTRODUCTION

A variety of research initiatives are attempting to reduce health inequities between men and women (1, 2). Research that includes sex- and gender-based analysis results in more accurate evidence, more relevant recommendations, more specifically-targeted interventions, and better outcomes (3-6). Sex differences are biology-linked differences between females and males caused by different sex chromosomes, sex-specific gene expression of autosomes, sex hormones, and their effects on organ systems (7). Gender differences arise from sociocultural processes such as the different behaviours of women and men, their exposure to environmental influences, impacts of nutrition, lifestyles or stress, and attitudes towards illness, treatment and prevention (7). Gender roles and gender identity are influenced by a complex interplay between genetic, endocrinal, and social factors (8). Finally, sex and gender are not straightforward binary categories. Many femininities and masculinities exist and can influence other important sociodemographic variables (9).

During their lifetime women are twice as likely as men to be diagnosed with depression. In contrast, three times as many men commit suicide (5, 10, 11). Recent evidence supports a link between type 2 diabetes (T2D) and depression, and shows that sex and gender are influential factors in this comorbidity (7, 9). The prevalence of depression in diabetic patients is higher in females than males (23.8% and 12.8%, respectively) (7). On the other hand, a pooled result from 32 studies stated that the risk of developing T2D in patients diagnosed with depression was higher in men than in women (RC=1.63 vs RC=1.29, respectively) (7, 12, 13). These differences are explained by biological differences and psychosocial factors such as body mass index, differences in the distribution of types of adipose tissue, an imbalance of sex hormones, socioeconomic status, psychosocial stress, and sleep deprivation (7, 9). Co-morbidity and mortality associated with the complications of T2D and depression are also different for men and women. For instance, men develop diabetic food syndrome at earlier ages and are more likely to have complications leading to amputations (7, 14). Women, on the other hand, have a higher risk of metabolic syndrome and fatal coronary heart disease than men (7, 15, 16). T2D and depression are also affected by gender differences, explained in part by the different behaviours associated

gender with representations of men and women, as well as their different perceptions of stress (17-19).

Despite the impacts of sex and gender differences on prevalence, diagnosis, treatment, outcomes, and equity, evidence on the importance of these differences has yet to be translated adequately into clinical training or practice (2, 5, 20). For example, a 2017 review suggested that only 35% of studies on Canadian practice guidelines, a cornerstone of knowledge translation, reported screening, diagnosis or management considerations specific to sex or gender, and only 25% used the terms "sex" and "gender" correctly (21).

Continuing professional development (CPD) is another cornerstone of knowledge translation as it mobilises professional and regulatory bodies as well as educational institutions to foster changes in clinical practice (22, 23). We argue that integrating sex and gender considerations into CPD is a promising avenue for addressing the inequities between men and women (5). We define CPD as all educational activities serving to maintain or increase the knowledge, skills, work performance, and relationships that a clinician needs to serve patients, the public or the profession. (5, 24, 25). Courses should be informed by theory-based factors known to influence the adoption of a given behaviour. Although one of several other factors influencing behaviour change, such as organisational constraints, intention is considered an acceptable proxy. Indeed, according to Godin's integrated model for health professional behaviour change, behavioural intention is the central influencing factor on behaviour adoption. In turn, this intention is under the influence of a number of other socio-cognitive factors (26). We aimed to assess the feasibility and impact of including sex and gender considerations in a CPD course on T2D and depression on health professionals' intention to include sex and gender considerations in patient care.

METHODS

Study design and setting

We conducted a non-randomised mixed-methods study with a concurrent embedded design: (1) a two-arm non-randomised controlled trial with post-intervention measures only; and (2) semi-structured group discussions following the CPD course. We used the

Theory of Planned Behaviour for quantitative analysis (27, 28), the Theoretical Domains Framework (TDF) for qualitative analysis (29, 30), and the COM-B (Capability, Opportunity, Motivation and Behaviour) model to triangulate findings (31). We followed the CONSORT extension for Pilot and Feasibility Trials Checklist to report results (32).

This project is one of six that were funded by the Canadian Institutes of Health Research to explore sex and gender issues in knowledge translation (33), gender transformative approaches to knowledge translation, and sex- and gender-based analysis (5, 33).

A multidisciplinary team was created of 25 researchers: two sex and gender specialists, three patient-partners with experience with T2D and/or mental health issues (two men and one woman), two physicians, one nurse, two CPD managers, one research assistant and two trainees. An executive committee of 12 team members (including all patient-partners) held monthly meetings addressing the main concerns in each research phase. They chose the clinical topic of the course based on needs expressed by CPD providers (see Innovation below). They then adapted an existing diabetes and depression CPD course to include sex and gender considerations and contacted CPD providers in three Canadian provinces to collaborate on implementing the courses.

Patient involvement

Three patient-partners, core members of the executive committee, contributed to governance (e.g., attending meetings and courses, making executive decisions) and innovation design. They contributed their experience to the CPD course, helped collect data and interpret results, coauthored this paper and advised us on plain language use for our presentations.

Participants and recruitment

All health professionals working in the clinical settings where our CPD course was advertised, including hospitals and family medicine groups, or participating in the continuing medical education (CME) conference where the course was to be offered, were invited to participate. Invitations were by email and through the Internet registration platforms of CME conferences in three Canadian provinces (Quebec, Ontario, New-Brunswick). Participants stayed in their respective groups for the semi-structured group

discussion that immediately followed the CPD course. Inclusion criteria were: practising health professionals available to participate in person for the whole course; and fluent in French (all our CPD courses were in French). Ethical approval was obtained from the Centre intégré universitaire de santé et de services sociaux de la Capitale-Nationale (CIUSSS-CN) Ethics Board (2017-2018-16 MP), the Hôpital Montfort Research ethics board (19-20-05-009), and the Vitalité Health Network research ethics board (CER-2019-18).

Innovation

Informed by a continuing medical education needs assessment by our key CPD stakeholder and partner, Médecins francophones du Canada (data not published), we chose patients with T2D and depression combined as the clinical topic, as physicians felt there was a gap in their education about this comorbidity. There is growing evidence of a link between T2D and depression and the importance of sex as a risk factor for this comorbidity (34-36). The team adapted an existing T2D and depression CPD course to include evidence-based sex and gender considerations. The original course, a 1-hour classroom-based activity, describes links between T2D and depression, reviews CANMAT 2016 Depression Guidelines and reviews pharmacological and non-pharmacological treatment of T2D and depression. This original course was used in the control group. Participants in the innovation group attended the same course but adapted to integrate sex- and gender-specific content including: 1) definitions and differences between the concepts of sex and gender, 2) epidemiological data on the differences in incidence, prevalence, morbidity and mortality between men and women with T2D and depression, and 3) a video explaining sex biases associated with these two conditions. The adapted CPD course (innovation) kept the original duration (one hour) and medical content of the original course (comparator). Links between T2D and depression were explained together with sex and gender differences, and reviews of pharmacological and non-pharmacological treatments were condensed. As per patient-partners' recommendations, we also held 30-minute semi-structured group discussions with both the innovation and control group immediately following the course. In the group discussion we presented a clinical case vignette on managing a patient with T2D and

depression in which the health professional's behaviour exhibited various divergences with best clinical practices. We asked participants to write down the main divergence and to categorise it within five categories determined by our team: 1) failure to mention positive factors for recovery, 2) failure to engage the patient in their health-related decision, 3) sex and gender biases, 4) failure to take into account notions of sex and gender, and 5) cannot be categorised. We prompted participants to discuss their perception of sex and gender considerations by linking them to the clinical vignette and to their clinical experience of integrating sex and gender considerations in general.

Depending on the setting (hospitals, family medicine groups, CME conferences) we either (1) assigned the participants to the control or innovation group on their arrival to achieve a balanced number of participants in both groups or (2) the participants registered in one group or the other, both groups being blinded to the innovation and control group. Thus participants entered the classroom for whichever course they signed up for. There was no communication between these groups, as the two courses were given simultaneously. Participants had all received the same invitation to attend a course on T2D and depression. There was no mention of sex and gender content before participants entered the room. Efforts were made to equally divide groups regarding number and gender of participants. At registration, participants were told that it was a research project that required their consent. Participants could attend the course and receive CME credits whether they chose to participate in the study or not. All CPD courses were delivered by the same two physicians (one man, assigned to the control group, and one woman, assigned to the innovation group) in all the research settings. We planned to offer six courses (three innovation and three control), two in each province (control and innovation simultaneously). Each course (both control and innovation) was a 45-minute lecture on T2D and depression followed by 15 minutes to fill in the CPD-Reaction questionnaire. An additional 30 minutes was planned for the semi-structured group discussion.

Outcome Measures

We assessed three feasibility outcome measures: recruitment, retention and adherence: 1) recruitment of >90 course participants for six courses and study participation rate of >70% (28, 37), 2) retention of CPD organisations, collaborators and patient-partners

throughout the project, 3) the holding of all planned CPD courses in all three provinces. Sample size was based on consultations with clinic managers and CPD providers and on practical considerations (e.g. average size of CPD courses, venues, the course being provided in French only).

We used CPD-Reaction (French version) to measure participants' behavioural intention to include sex and gender considerations in patient care. CPD-Reaction is a self-administered questionnaire (Cronbach α 0.79–0.89) (38, 39). Twelve items measure five constructs determined through a systematic review of theory-driven studies of behaviour change in health professionals: 1) behavioural intention, 2) beliefs about capabilities, 3) social influences, 4) beliefs about consequences, and 5) moral norm (37). The score for each construct is computed as the average of each item (Likert scale of 1 to 7), except for social influence, which is rated on a Likert scale of 1 to 5 (28). There is no global score. Finally, in group discussions, we identified barriers and facilitators to including sex and gender considerations in caring for patients with T2D and depression and mapped them onto the TDF. The TDF was developed through a consensus of experts who consolidated 33 psychosocial theories of behaviour change to generate 14 domains (40).

Data collection

Quantitative data were collected post-intervention with the CPD-Reaction questionnaire and sociodemographic questions (38). Semi-structured qualitative discussion took place in both innovation and control groups after the questionnaires were completed so as not to influence quantitative results. In both innovation and control groups, discussions were recorded and transcribed.

Analysis

Quantitative analysis

Categorical variables were described by reporting absolute (n) and relative (%) frequencies. Continuous variables were described by their measure of central tendency (mean and/or median) and dispersion (standard deviation and percentiles). Covariance analysis was used to compare the scores of the innovation and control groups. As the intention did not have a perfectly Gaussian distribution, we also compared intention

scores using Wilcoxon's non-parametric analysis and used the Kruskal-Wallis test to compare medians. We used Spearman's rank test to assess the correlation between the intention scores and psychosocial factors (social influence, beliefs about capabilities, moral norms, beliefs about consequences). We used general linear models to assess whether the intention score varied significantly from the control group to innovation group after adjusting for confounding factors. These factors were identified using the 10% change in the regression coefficient associated with the exposure variable (41, 42). However, to increase the appearance validity of the model, we constructed a separate model in which we forced age, gender and practice environment. SAS software (version 9.4) was used for all statistical analyses. The empirical significance threshold (P value) was set at 0.05 in bilateral analysis.

Qualitative analysis

The discussion transcripts were imported into N'Vivo V.12 for analysis. Using the TDF as a guide, two researchers reviewed and agreed on codes and data were simultaneously coded using a thematic deductive approach (ADT, AGo) (43). Data were then refined into TDF domains. As the discussion occurred in French, all illustrative quotes were translated into English by a master's student (ADT) and reviewed by a scientific translator. We calculated the frequency of each barrier and facilitator by recording the number of times it was mentioned in the four group discussions (GDs 1 to 4).

Triangulating quantitative and qualitative data

We triangulated quantitative and qualitative data to propose practical theory-driven recommendations for improving our CPD innovation (44). We compared the five psychosocial determinants measured in the CPD-Reaction questionnaire to the domains of the TDF. We observed where quantitative and qualitative data converged, where they offered additional information on the same constructs, and where they diverged. We derived recommendations using the COM-B model of behaviour (45). COM-B proposes three criteria essential for a behaviour to occur: capacity, opportunity and motivation (46). The subcategories of these criteria can be linked to the TDF domains and their associated barriers or facilitators. The COM-B also proposes nine intervention functions assigned to TDF domains that can prompt behaviour change: education, persuasion, incentivisation,

coercion, training, restriction, environmental restructuring, modelling and enablement (31, 45, 47). Recommendations were made by identifying which of these intervention functions matched our results and then selecting relevant function-associated behaviour change techniques (45).

RESULTS

Recruitment and participant characteristics

We offered the 12 CPD courses (i.e. six innovation/control pairs) in each of three Canadian provinces: Quebec, Ontario and New Brunswick. Four pairs of courses were held in Quebec (two in Montreal, October 10th 2018 and October 30th 2019, and two in Quebec City, October 17th 2019 and January 29th 2019), one in Ontario (Ottawa, November 8th 2019) and one in New-Brunswick (Moncton, October 4th 2019).

Figure 1 illustrates the flow of participants. The participation rate (ratio of users who participated in the study to those who took the training) was 71% (127/178). Forty-nine of 92 questionnaires were analysed from the innovation groups and 78 of 86 from the control groups. Most participants were under 44 years old (n=80, 63%), women (n=101, 79.5%), practised in French (n=86, 67.7%), in Quebec (n=85, 66.9%) and in an urban setting (n=100, 78.8%) (**Table 1**).

Table 1: Sociodemographic characteristics of the participants in innovation and control groups

	TOTAL	**Innovation Group**	**Control Group**
No. of Participants	127	49	78
Age (years)*			
<44	80 (63.0)	28 (57.1)	52 (66.7)
≥ 45	42 (33.1)	19 (38.8)	23 (29.5)
Missing data	5 (3.9)	2 (4.1)	3 (3.8)

Gender*			
Women	101 (79.5)	40 (81.6)	61 (78.2)
Men	19 (15.0)	7 (14.3)	12 (15.4)
Missing data	7 (5.5)	2 (4.1)	5 (6.4)
Language of practice*			
French	86 (67.7)	32 (65.2)	54 (69.2)
Other	36 (28.3)	15 (30.6)	21 (26.9)
Missing data	5 (4.0)	2 (4.1)	3 (3.9)
Province of practice			
Quebec	85 (66.9)	31 (63.2)	54 (69.3)
Ontario	18 (14.2)	9 (18.4)	9 (11.5)
New Brunswick	16 (12.6)	7 (14.3)	9 (11.5)
Missing data	8 (6.3)	2 (4.1)	6 (7.7)
Practice environment*			
Urban	100 (78.8)	39 (79.6)	61 (78.2)
Rural	14 (11.0)	4 (8.2)	10 (12.8)
Missing data	13 (10.2)	6 (12.2)	7 (9.0)

*n(%)

Quantitative results

Feasibility

We recruited a total of 127 participants, a 41% increase from our target of 90 participants. Collaborators and executive committee members remained involved throughout the project. We held monthly executive committee meetings as planned. Our CPD trainings

were held in the three provinces as planned. We gave 12 courses instead of the six initially planned, as additional organisations in Quebec City (n=1) and Montreal (n=2) showed interest. Due to time constraints imposed by CME settings, completing 1.5 hours (45-min course, 15-min evaluation and 30-min discussion) in all settings was not possible, therefore we held the group discussions in only two out of the six settings (Montreal and Ottawa).

Behavioural Intention

The innovation aims to influence behaviour by modifying intention and its psychosocial determinants. For example, the innovation could change beliefs about capabilities (or confidence) by increasing health professionals' knowledge about the desired behaviour. **Table 2** shows scores for intention and its psychosocial determinants for innovation and control groups as evaluated using the CPD-Reaction questionnaire. Mean difference between innovation and control scores for the four psychosocial determinants of behaviour change influencing intention were: MD=0.16 for social influence (95% CI: -0.26, 0.58), MD=0.63 for belief about capabilities (95% CI: 0.21, 1.06), MD=0.25 for moral norm (95% CI: -0.21, 0.72) and MD=0.22 for belief about consequences (95% CI: -0.23, 0.67). The mean intention score for including sex and gender considerations in patient care was higher in the innovation than in the control group, i.e. 5.65 (± 0.19) versus 5.19 (±0.15), on a scale from 1 (low) to 7 (high). The mean difference between the two groups was -0.47 (95% CI: -0.95, 0.01), with a p-value of 0.06 (**Supplementary table 1**). No statistically significant differences were observed for the remaining four psychosocial determinants. Bivariate analysis showed that the higher median for intention was significantly associated with age over 45 (p=0.03) and a rural practice environment (p=0.02) (**Supplementary table 1**). After adjusting for age, gender and practice environment, the mean difference in intention between the two groups was statistically significant: -0.57 (95% CI: -1.09, -0.05), with a p-value of 0.03 (**Table 3**).

Table 2: CPD-Reaction questionnaire mean scores

	Total	**Innovation**	**Control**	**Difference (95% CI)**
No. of participants	127	49	78	-

Psychosocial determinants – score range (1 to 7)*				
Social influence	4.62 (4.42; 4.83)	4.72 (4.44; 5,00)	4.56 (4.27; 4.85)	0.16 (-0.26; 0.58)
Beliefs about capabilities	5.1 (4.90; 5.33)	5.50 (5.27; 5.74)	4.87 (4.56; 5.17)	0.63 (0.21; 1.06)
Moral norm	5.90 (5.69; 6.13)	6.06 (5.80; 6.32)	5.81 (5.48; 6.14)	0.25 (-0.21; 0.72)
Beliefs about consequences	5.68 (5.46; 5.90)	5.82 (5.52; 6.11)	5.60 (5.28; 5.91)	0.22 (-0.23; 0.67)
Intention*	5.37 (5.13; 5.60)	5.65 (5.36; 5.95)	5.19 (4.85; 5.52)	0.47 (-0.01; 0.95)

*Mean (95% CI) ;

Table 3: Mean difference of the intention score between innovation and control groups

	Model 1*		**Model 2†**		**Model 3‡**	
	β (95% CI)	**P Value**	**β (95% CI)**	**P Value**	**β (95% IC)**	**P Value**
Control	Reference		Reference		Reference	
Innovation	-0.47 (-0.95;0.01)	**0.057**	-0.61 (-1.10;-0.12)	**0.015**	-0.57 (-1.09;-0.05)	**0.031**

95% CI, confidence interval at 95%;
*Non-adjusted;
†Adjusted for age and gender;
‡Adjusted for age, gender and environment of practice.

Qualitative findings

Due to time constraints imposed by CME settings, we held the group discussions in two out of the six settings, Montreal, October 30th 2019 and Ottawa, November 8th 2019. Thus

four semi-structured group discussions (GD1, GD2, GD3, GD4) were conducted and 67 health professionals participated, reporting a variety of barriers and facilitators (**Table 4)**.

Table 4: Mapping facilitators and barriers to the Theoretical Domains Framework (TDF) with illustrative quotes and frequencies

TDF DOMAIN	FACILITATOR/ BARRIER	ILLUSTRATIVE QUOTES*	FREQUEN-CIES** (N=4 groups)
Skills	The health professional acknowledges different treatment methods by gender (Facilitator)	"Dominique, is that a man or a woman? … Because they are probably not treated the same" (GD4)	4
	The health professional acknowledges different clinical representation by gender (Facilitator)	"…I work as a nurse in cardiac and pulmonary rehabilitation, and … it is a fact, that women come less [to rehabilitation programs] in general than men. Women often will quit [rehabilitation] or they won't come because they're taking care of everyone. But something happens [illness] and then they don't have time to take care of themselves, because it's too much" (GD3)	1
	The health professional assumed the gender of the patient when analysing a clinical vignette (Barrier)	"I assumed that it was a guy" (GD3) / "I presumed that it was a girl" (GD4)	3
Beliefs about Capabilities	The health professional feels he/she can accurately observe the phenotype of the patient (Facilitator)	"At the first contact we have with a patient … we see the phenotype there without talking about gender, it's one of the things that jumps out at you when you're taking notes." (GD3)	3
Social influences	The health professionals assume the patient's gender based on his/her societal role (Barrier)	"I heard 'civil servant', I don't know, in my head I was like 'civil servant', so it's a man." (GD4)	3
Knowledge	The health professional knows the differences between sex and gender in scientific	"Yes, that's it actually, the biological aspect you certainly take into account in the study, but we are talking about the [social] categories of sex and gender… And	2

	literature (Facilitator)	menopause, and on the other hand [there's] also andropause" (GD2)	
	The health professional did not ask the gender of the patient when analysing a clinical vignette (Barrier)	"Well, I don't know why we didn't note it [the gender of the patient], I don't have the answer to that. But … when we talk about the clinical context it is systemically noted in the first … sentence, in the first two words [of notes documenting a consultation]. It's hard to say that we ignore it [gender of the patient]. We didn't notice it here, but in clinical practice, have you ever met a patient without identifying their gender?" (GD3)	2 1
	The health professional is not aware of the concepts of sex and gender when analysing a clinical vignette (Barrier)	"…but in the seminar, there was no emphasis on that, so it didn't jump out at us," (GD3)	
Beliefs about Consequences	The health professional mentions that they would not change their therapeutic approach according to the patient's gender (Barrier)	"I would say that I didn't see the need to know if it was a man or a woman…I never asked myself the question..." (GD1)	2
Environmental Context and Resources	The patient's sex is routinely recorded in medical notes (Facilitator)	"… in the clinical context it's [the sex of the patient] systematically noted in the first lines in every consultation. In the first sentence, in the first two words. It's hard to say that we ignore it." (GD3)	2
	The androcentric nature of the French language (the use of masculine generic language to refer to men and women, as well as other gender representation) (Barrier)	"In French everything is masculine until you know, like in the room here [mostly women participants] we'll say like "ils ont fait ça" [*ils* is a masculine pronoun] because you are the only men, but…" [generalizing to the masculine pronoun] (GD3) / "The language doesn't help … [to differentiate between men and women]." (GD3)	1
	The healthcare professional perceives that the language used by	"Well it's about when you say 'our diabetes' and 'your depression', if it had been a woman would we have said the same thing?… 'your depression' 'our diabetes'..." (GD2)	1

	physicians towards a patient may be different according to sex and gender (Barrier)	[referring to the bias in the language to describe 'your' depression versus 'our' diabetes]	
Social/Professional Role and Identity	The health professional reflects positively on his/her relationship with the patient (Facilitator)	"I work in an exclusively white environment, and I am the only black person, and I have no problem whether [the patient] is male, female or a child" (GD3)	1
Intentions	The health professional has the intention to change his/her therapeutic approach by considering the differences of gender (Facilitator)	"With the information that I have here [clinical description of vignette], if I had 'menopaused woman', then I think I would have researched more, but with what I had here, I didn't [see the need]." (GD4)	1
	The health professional does not have the intention to change his/her therapeutic approach by considering the differences of gender (Barrier)	"With what I have here [descriptive information of the clinical vignette], I am not sure to what extent I would have changed my approach" (GD4)	1
Goals	The health professional does not perceive the integration of the concepts of sex and gender in clinical practice as a priority (Barrier)	"It wasn't important … the most important, [but] that doesn't mean that [the lack of sex and gender consideration in the clinical vignette] wasn't perceived" (GD4)	1
Memory, Attention and Decision Processes	The health professional does not consider that sex and gender are necessary parts of the decision-making process (Barrier)	"If it is not obvious, we are not inclined to do it… [take into consideration the sex and gender of the patient]" (GD2)	1

*Free translation from French

**The number of times that the barrier/facilitator appeared in the transcript

Barriers and facilitators mapped to the TDF domains

Ten barriers mapped to nine of the 14 TDF domains and seven facilitators mapped onto six of the domains. The most frequent barriers were related to Skills (e.g. failing to consider a

patient's gender) (n=3) and to Social Influence (e.g. making gender assumptions about employment) (n=3). The most frequent facilitators were also related to Skills (n=4) (**Table 4**).

We mapped to the Skills domain when the participants asked whether their patient was a woman or man before analysing the clinical vignette, or else failed to ask the question (the fictive name of the patient – Dominique – was strategically ambiguous). Thus, failure to ask was coded as a barrier, and asking was coded as a facilitator. Discussion about information on sex and/or gender was coded as a facilitator in the Knowledge domain, but reporting differentiating between women and men patients in clinical practice was coded as a facilitator in the Skills domain. When participants reported not needing to know the patient's gender because this information would not have changed their intervention, we mapped the barrier to Beliefs about consequences domain. Participants documented some differences between men and women patients in their clinical practice, demonstrating ability acquired through practice to include sex and gender considerations. Participants also reported they did not ask the sex of the patient in the clinical vignette as they automatically observe a patient's sex in practice, so didn't feel the need to mention it in this context. This facilitator was mapped to the domain beliefs about capabilities (n=3). Some participants reported that they routinely observe and record a patient's sex when taking notes. This facilitator was mapped to the domain environmental context and resources, since it this is an institutional practice reflecting an organisational clinical culture, and could foster further awareness and consideration of sex and gender (**Table 4**).

Triangulation

CPD-Reaction psychosocial variables matched barriers that mapped onto to the TDF domains beliefs about consequences, social influence and intentions. CPD-Reaction psychosocial variables also matched facilitators that mapped onto to the TDF domains beliefs about capabilities and intentions. We identified six additional psychosocial variables from the TDF: knowledge, skills, goal, memory, attention and decision processes, environmental context and resources, social/professional role and identity. Results of triangulation were summarised with consequent recommendations (**Supplementary table 2)**. Recommendations for improving the CPD training were based on behaviour change

techniques associated with the following functions: modelling, training, environmental restructuring, enablement, education and goal settings (**Supplementary table 2)** (45). Training (n=5) and education (n=4) were the most frequent functions used in the recommendations.

DISCUSSION

We assessed the feasibility and impact of including sex and gender considerations in a CPD course on T2D and depression care on health professionals' intention to include sex and gender considerations in patient care. Recruited CPD organisations, collaborators and patient-partners stayed engaged throughout the study. All planned activities occurred and 71% of targeted health professionals participated. The intention to include sex and gender considerations in patient care was higher in the innovation group, and statistically significant when controlling for age, gender, and practice sites. Barriers were mostly related to skills and social influence and facilitators to skills and beliefs about capabilities. We triangulated results and produced recommendations for improving the CPD course. The following observations could enable CPD organisations to systematically improve CPD by integrating sex and gender considerations into their existing material.

First, all our predetermined feasibility criteria were met. In fact, due to increased interest in the topic, we recruited more participants and gave more CPD activities than planned. Recruitment may also have improved because we involved stakeholders early on in the research process, including in applying for the grant. Early engagement of stakeholders has been associated elsewhere with more successful recruitment (48). Therefore, elements that should be considered when designing similar CPD activities include, but are not limited to: 1) successful collaboration and co-creation with CPD organisations early on including during grant writing, 2) offering CME accreditation for the CPD activities, 3) the duration of the training, and 4) the evidence base relevant to the clinical topic (49).

Second, the CPD course that included sex and gender considerations increased health professionals' intention to include sex and gender considerations in patients' care. This may suggest a significant knowledge gap among participants. Studies show that health professionals lack knowledge of sex and gender differences in disease manifestation and outcomes and fail to recognize the gender constraints that their patients face (50-53). For

example, in a cross-sectional survey of physicians (71% male), 55% said that the medical curriculum did not adequately prepare them for dealing with sexual health problems, particularly those of female patients (50). In another study, only 49% of primary care physicians (n=200, 65% male) and 59% of cardiologists (n=100, 85% male) reported that their training prepared them to assess female patients' cardiovascular risk (52). Our study represents a promising avenue for rectifying these gaps. Furthermore, bivariate analyses of the between-group difference in the intention scores yielded significant results in older, but not younger, participants and in those practising in rural area. Their age and geographical isolation perhaps reduced their exposure to sex and gender issues, which have only been included in medical curricula since they qualified (53). They may also have less access to CPD training due to isolation, poor technological resources, low financial support (54, 55) and geographical variations in medical practice styles (56, 57). Future studies could further investigate the perceptions of health professionals in rural settings on age and gender. They could also document if patients experience geographical differences in care regarding sex and gender. Training could target older and rural health professionals, who seemed more open to modifying their clinical practice.

Third, beliefs about capabilities as a facilitator showed the strongest mean difference between the innovation and control groups. These results are consistent with a literature review of 277 studies showing that the mechanisms of action most frequently associated with behaviour change techniques are beliefs about capabilities and intention (58). Adding a practical component to the CPD course could strengthen beliefs about capabilities. Also, several barriers and facilitators to considering sex and gender in patient care were identified. Our qualitative analysis showed that participants did not consider integrating sex and gender into clinical practice as a priority, with social influences emerging as an important barrier. The social influence score as measured by CPD-Reaction also showed the lowest impact (MD=0.16), suggesting that the training did not address this factor (Table 2). A CPD course could offer a reflective segment on how social influence could be affecting their clinical practice (57, 59). Furthermore, belief about consequences had one of the lowest MD (0.22) of the five psychosocial determinants, and one associated barrier (n=2). This could be remedied by focusing more on the consequences of not integrating sex and gender into clinical practice (51).

Finally, in spite of the low priority given to sex and gender by our participants, qualitative analysis demonstrated that opportunities already exist for integrating these considerations into practice, such as the routine documenting of the patient's sex. CPD strategies could make more of these opportunities (60). For example, CPD activities could advocate for sex- and gender-adapted care when treating men and women for diabetes and depression. Indeed, specific attention could be given to diabetic foot care when treating men, while specific attention could be given to blood-glucose regulation and to family and lifestyle issues when treating women (7, 61).

This innovation could be adapted to medical fields other than T2D and depression, and to other countries and areas outside French-speaking provinces of Canada. While many of the barriers participants mentioned were culture- and language-specific to the Quebec or francophone context, many other languages (e.g. Spanish, German, Italian, and Portuguese) also generalise everything to the masculine gender, suggesting shared linguistic barriers. However, each culture has highly specific sex and gender norms affecting physicians' clinical assumptions (62). Our qualitative results highlight the fact that CPD on sex and gender considerations must be tailored to specific cultural contexts (17) and incorporate sex- and gender-based analysis tools (63).

Our study has a few limitations. As we used a single post-intervention measure, we cannot attribute the difference between the two groups solely to the innovation. However, our analysis suggests that those who completed the innovation increased their intention, as well as increasing all four psychosocial predictors, suggesting an association with the innovation. Second, the fact that participants could choose which course to attend (according to conference guidelines), and hence the non-randomised nature of the study, may have biased our feasibility findings. Third, the training was given by teachers of different genders for the innovation and control groups (a woman in the innovation group and a man in the control group). As a bias could have been introduced owing to differences in communication styles between men and women, the teaching teams practised the courses several times to ensure that teaching methods were equivalent. In addition, we ensured the teachers stayed with their respective groups for the six data collections. Fourth, due to ethics guidelines, we only analysed questionnaires completed by participants who had also

signed consent forms. Although the human resources for both groups were the same (trainer, research-assistant and patient-partners), the control group had an extra team member, resulting in unequal numbers of participants who signed consent in each group. The presence of this extra member could also explain the difference in the number of questionnaires collected in the two groups. Fifth, our study had low participation rates, although it did meet our feasibility target sample size given the logistical and contextual constraints. Recruitment followed the way CPD activities are usually publicised in large organisations (a scattershot approach that includes posters, calendars, mass emailing), thus the participation rate did not necessarily reflect a lack of interest. Our study approach was pragmatic, i.e. it took place in a real CPD training setting. This pragmatic study will inspire other health services researchers and implementation scientists to collaborate with CPD stakeholders and knowledge users to embed their studies in real CPD training settings. Sixth, although there is evidence that intention is an effective determinant for measuring behaviour change (39), it is limited as a proxy. Finding other reliable measures of behaviour change is challenging (64). However, identifying barriers and facilitators to change is a first step (64). Semi-structured group discussions using a clinical vignette have also been shown to contribute to clinical behaviour change (64). Methods such as audit and feedback, as well as "commitment to change statements" could reduce the intention-behaviour gap and strengthen the understanding of clinical changes following CPD activities (65, 66). Lastly, our discussion groups attracted many participants, limiting both participants' opportunity to speak and the depth of the discussion. Our mixed-methods approach is a strength of this study and our findings support the feasibility of a randomised trial informed by identified barriers and facilitators.

CONCLUSION

A CPD course with sex and gender considerations is feasible and well received by health professionals. The significant between-group difference in the intention scores suggests the innovation had a favorable impact on health professionals' intention to include sex and gender considerations when caring for their patients with T2D and depression. However, caution is required in interpreting our results as this effect may be attributed to other sources given the non-randomised nature of our study. Future randomised controlled trials

are needed to control for potential selection biases to confirm our results and identify barriers and facilitators in sex- and gender-adapted diabetes and depression care. Our findings will inform future CPD initiatives that address this topic and other inequities in health care pertaining to sex and gender.

Figure Legend

Figure 1: Flowchart of participants

*This is an approximate figure given the changing dynamics of the hospital's professional environment; an email was sent to 2000 employees including healthcare professionals, others were invited using posters in the training sites, oral communication at a meeting with the organizing team of the clinical setting, and announcements in Médecins francophones du Canada's conference calendar.

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ADT, AGo, SGB, FL, NP and AB conceived and designed the study. ADT, AGo, SGB, DA, AGa, DRL, LV and FL participated to data collection. ADT, AGo, SGB, GN and FL participated to data analysis. All authors critically revised the interpretation of data. ADT, AGo, SGB and FL drafted the manuscript. All authors and members of the mATrICES-F Group read, provided feedback and approved the final manuscript.

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Disclaimer

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Competing interests

None declared.

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References

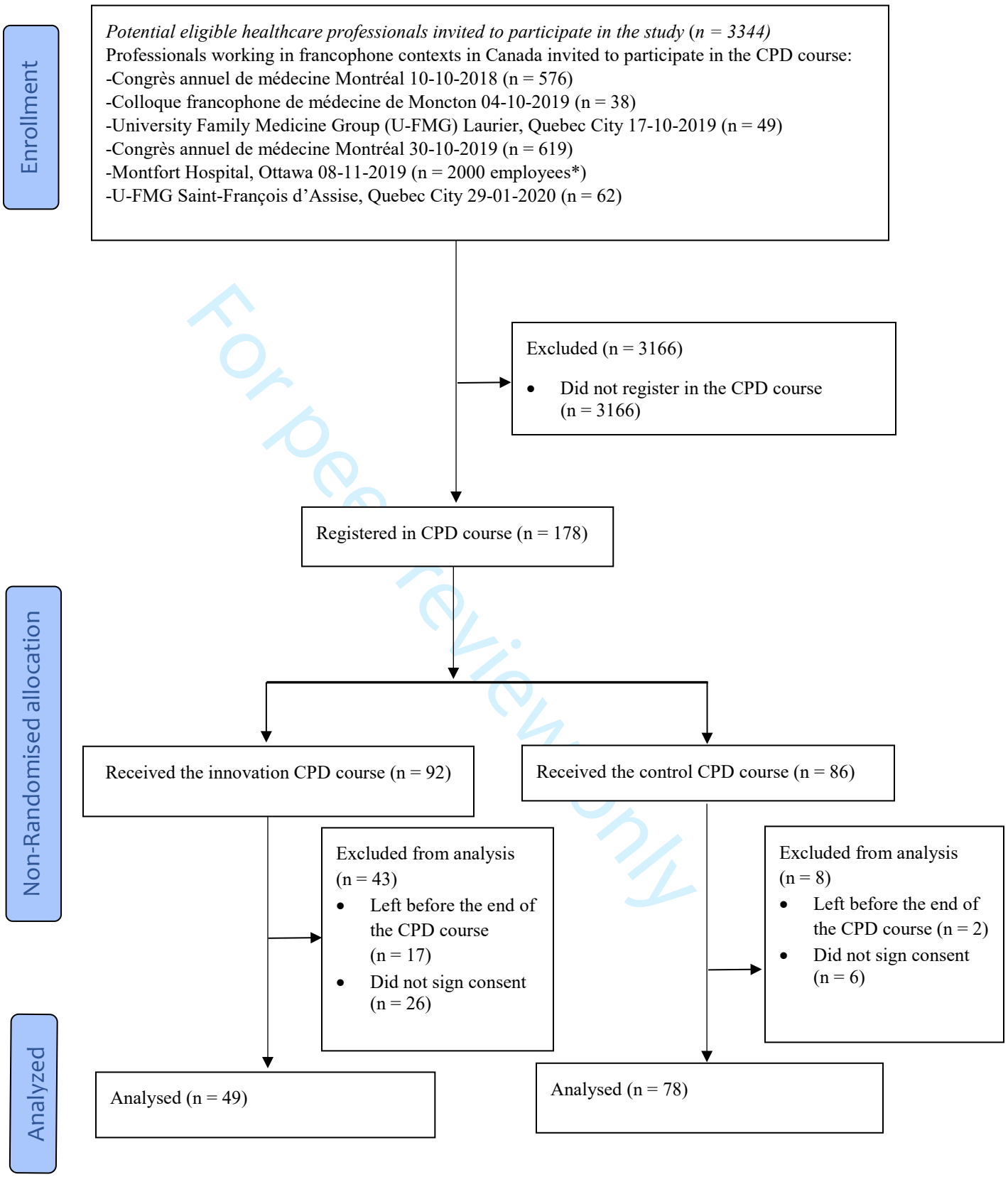
1. Clayton JA, Tannenbaum C. Reporting Sex, Gender, or Both in Clinical Research? JAMA. 2016;316(18):1863.
2. Institut de recherche en santé du Canada. Comment intégrer le sexe et le genre à la recherche 2019 [Available from: http://cihr-irsc.gc.ca/f/50836.html.
3. Johnson JL, Greaves L, Repta R. Better science with sex and gender: Facilitating the use of a sex and gender-based analysis in health research. International Journal for Equity in Health. 2009;8(1):14.
4. Oliffe J, Greaves L. Designing and Conducting Gender, Sex, and Health Research. Thousand Oaks, California2012. Available from: http://sk.sagepub.com/books/designing-and-conducting-gender-sex-and-health-research.
5. Légaré F, Lee-Gosselin H, Borduas F, Monette C, Bilodeau A, Tanguay D, et al. Approaches to considering sex and gender in continuous professional development for health and social care professionals: An emerging paradigm. Medical Teacher. 2018;40(9):875-9.
6. Tannenbaum C, Ellis RP, Eyssel F, Zou J, Schiebinger L. Sex and gender analysis improves science and engineering. Nature. 2019;575(7781):137-46.
7. Kautzky-Willer A, Harreiter J, Pacini G. Sex and Gender Differences in Risk, Pathophysiology and Complications of Type 2 Diabetes Mellitus. Endocrine Reviews. 2016;37(3):278-316.
8. Geary N. Counterpoint: physiologists should not distinguish "sex" and "gender". American Journal of Physiology-Regulatory, Integrative and Comparative Physiology. 2010;298(6):R1702-R4.

9. Demmer RT, Gelb S, Suglia SF, Keyes KM, Aiello AE, Colombo PC, et al. Sex Differences in the Association Between Depression, Anxiety, and Type 2 Diabetes Mellitus. 2015;77(4):467-77.
10. Kuehner C. Why is depression more common among women than among men? Lancet Psychiatry. 2017;4(2):146-58.
11. Turecki G, Brent DA. Suicide and suicidal behaviour. The Lancet. 2016;387(10024):1227-39.
12. Zhuang QS, Shen L, Ji HF. Quantitative assessment of the bidirectional relationships between diabetes and depression. Oncotarget. 2017;8(14):23389-400.
13. Ali S, Stone MA, Peters JL, Davies MJ, Khunti K. The prevalence of co-morbid depression in adults with Type 2 diabetes: a systematic review and meta-analysis. Diabetic Medicine. 2006;23(11):1165-73.
14. Ahmad A, Abujbara M, Jaddou H, Younes NA, Ajlouni K. Anxiety and Depression Among Adult Patients With Diabetic Foot: Prevalence and Associated Factors. Journal of clinical medicine research. 2018;10(5):411-8.
15. Toker S, Shirom A, Melamed S. Depression and the metabolic syndrome: gender-dependent associations. Depression and anxiety. 2008;25(8):661-9.
16. Möller-Leimkühler AM. Gender differences in cardiovascular disease and comorbid depression. Dialogues in clinical neuroscience. 2007;9(1):71-83.
17. Coen S BE. What a Difference Sex and Gender Make: A gender, Sex and Health Research Casebook. Vancouver; 2012.
18. Gilbert-Ouimet M, Trudel X, Aubé K, Ndjaboue R, Duchaine C, Blanchette C, et al. Differences between women and men in the relationship between psychosocial stressors at work and work absence due to mental health problem. Occupational and Environmental Medicine. 2020;77(9):603-10.
19. Deischinger C, Dervic E, Leutner M, Kosi-Trebotic L, Klimek P, Kautzky A, et al. Diabetes mellitus is associated with a higher risk for major depressive disorder in women than in men. BMJ Open Diabetes Research & Care. 2020;8(1):e001430.
20. Tannenbaum C, Greaves L, Graham ID. Why sex and gender matter in implementation research. BMC Medical Research Methodology. 2016;16(1).
21. Tannenbaum C, Clow B, Haworth-Brockman M, Voss P. Sex and gender considerations in Canadian clinical practice guidelines: a systematic review. CMAJ Open. 2017;5(1):E66-E73.
22. Ferlie EB, Shortell SM. Improving the quality of health care in the United Kingdom and the United States: a framework for change. Milbank Q. 2001;79(2):281-315.
23. Davis D, Evans M, Jadad A, Perrier L, Rath D, Ryan D, et al. The case for knowledge translation: shortening the journey from evidence to effect. Bmj. 2003;327(7405):33-5.
24. Davis D, Galbraith R. Continuing Medical Education Effect on Practice Performance. Chest. 2009;135(3):42S-8S.
25. Institute of Medicine. Redesigning Continuing Education in the Health Professions. Washington, DC: The National Academies Press; 2010. 296 p.
26. Godin G. Les comportements dans le domaine de la santé : Comprendre pour mieux intervenir. Montréal, Québec: Les Presses de l'Université de Montréal 2012.

27. Ajzen I. The theory of planned behavior. Organizational Behavior and Human Decision Processes. 1991;50(2):179-211.
28. Légaré F, Borduas, F., Freitas, A., Turcotte, S. User Manual – The Continuing Professional Development (CPD) Reaction Questionnaire. 2015.
29. Atkins L, Francis J, Islam R, O'Connor D, Patey A, Ivers N, et al. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. Implementation Science. 2017;12(1).
30. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. Implementation Science. 2012;7(1):37.
31. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. Implementation Science. 2011;6(1):42.
32. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355:i5239.
33. Gogovor A MT, Etherington N, Colantonio A, Légaré F, on behalf of the GIKT Group. Sex and gender analysis in knowledge translation interventions: challenges and solutions. Health Research Policy and Systems. 2020;18(1):108.
34. Atlantis E, Fahey P, Foster J. Collaborative care for comorbid depression and diabetes: a systematic review and meta-analysis. BMJ Open. 2014;4(4):e004706.
35. Holt RI, de Groot M, Golden SH. Diabetes and depression. Curr Diab Rep. 2014;14(6):491.
36. Harreiter J, Fadl H, Kautzky-Willer A, Simmons D. Do Women with Diabetes Need More Intensive Action for Cardiovascular Reduction than Men with Diabetes? Current diabetes reports. 2020;20(11):61.
37. Légaré F, Freitas A, Turcotte S, Borduas F, Jacques A, Luconi F, et al. Responsiveness of a simple tool for assessing change in behavioral intention after continuing professional development activities. PLOS ONE. 2017;12(5):e0176678.
38. Légaré F, Borduas F, Freitas A, Jacques A, Godin G, Luconi F, et al. Development of a Simple 12-Item Theory-Based Instrument to Assess the Impact of Continuing Professional Development on Clinical Behavioral Intentions. PLoS ONE. 2014;9(3):e91013.
39. Godin G, Bélanger-Gravel A, Eccles M, Grimshaw J. Healthcare professionals' intentions and behaviours: A systematic review of studies based on social cognitive theories. Implementation Science. 2008;3(1):36.
40. Michie S. Making psychological theory useful for implementing evidence based practice: a consensus approach. Quality and Safety in Health Care. 2005;14(1):26-33.
41. Mickey R M GS. The Impact of Confounder Selection Criteria on Effect Estimation American Journal of Epidemiology. 1989;129(1):125-37.
42. Budtz-Jørgensen E, Keiding N, Grandjean P, Weihe P. Confounder selection in environmental epidemiology: assessment of health effects of prenatal mercury exposure. Ann Epidemiol. 2007;17(1):27-35.
43. Atkins L, Francis J, Islam R, O'Connor D, Patey A, Ivers N, et al. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. Implement Sci. 2017;12(1):77.

44. O'Cathain A, Murphy E, Nicholl J. Three techniques for integrating data in mixed methods studies. Bmj. 2010;341:c4587.
45. Michie S, Atkins L, R. W. The behaviour change wheel : a guide to designing Interventions. Great Britain: Silverback Publishing; 2014.
46. West R, Michie S. A brief introduction to the COM-B Model of behaviour and the PRIME Theory of motivation. Qeios. 2020.
47. Agbadjé TT, Menear M, Dugas M, Gagnon M-P, Rahimi SA, Robitaille H, et al. Pregnant women's views on how to promote the use of a decision aid for Down syndrome prenatal screening: a theory-informed qualitative study. BMC Health Services Research. 2018;18(1).
48. Garvelink MM, Freitas A, Menear M, Brière N, Stacey D, Légaré F. In for a penny, in for a pound: the effect of pre-engaging healthcare organizations on their subsequent participation in trials. BMC Research Notes. 2015;8(1):751.
49. Little P, Hayes S. Continuing professional development (CPD): GPs' perceptions of post-graduate education-approved (PGEA) meetings and personal professional development plans (PDPs). 2003;20(2):192-8.
50. Veloshnee G, Loveday P-K. Gender biases and discrimination: a review of health care interpersonal interactions 2007 [Available from: https://www.who.int/social_determinants/resources/gender_biases_and_discrimination_wgkn_2007.pdf.
51. Mauvais-Jarvis F, Bairey Merz N, Barnes PJ, Brinton RD, Carrero J-J, Demeo DL, et al. Sex and gender: modifiers of health, disease, and medicine. The Lancet. 2020;396(10250):565-82.
52. Bairey Merz CN, Andersen H, Sprague E, Burns A, Keida M, Walsh MN, et al. Knowledge, Attitudes, and Beliefs Regarding Cardiovascular Disease in Women: The Women's Heart Alliance. J Am Coll Cardiol. 2017;70(2):123-32.
53. Kling JM, Rose SH, Kransdorf LN, Viggiano TR, Miller VM. Evaluation of sex- and gender-based medicine training in post-graduate medical education: a cross-sectional survey study. Biology of Sex Differences. 2016;7(S1).
54. Curran VR, Fleet L, Kirby F. Factors influencing rural health care professionals' access to continuing professional education. Aust J Rural Health. 2006;14(2):51-5.
55. Berndt A, Murray CM, Kennedy K, Stanley MJ, Gilbert-Hunt S. Effectiveness of distance learning strategies for continuing professional development (CPD) for rural allied health practitioners: a systematic review. BMC Medical Education. 2017;17(1).
56. OCDE. Geographic Variations in Health Care2014.
57. Bertakis KD, Helms LJ, Callahan EJ, Azari R, Robbins JA. The influence of gender on physician practice style. Med Care. 1995;33(4):407-16.
58. Carey RN, Connell LE, Johnston M, Rothman AJ, de Bruin M, Kelly MP, et al. Behavior Change Techniques and Their Mechanisms of Action: A Synthesis of Links Described in Published Intervention Literature. Annals of Behavioral Medicine. 2018;53(8):693-707.
59. Etherington N, Rodrigues IB, Giangregorio L, Graham ID, Hoens AM, Kasperavicius D, et al. Applying an intersectionality lens to the theoretical domains framework: a tool for thinking about how intersecting social identities and structures of power influence behaviour. BMC Medical Research Methodology. 2020;20(1).

60. Guly HR. Continuing professional development for doctors in accident and emergency. Journal of Accident & Emergency Medicine. 2000;17(1):12-4.
61. Peek ME. Gender differences in diabetes-related lower extremity amputations. Clinical orthopaedics and related research. 2011;469(7):1951-5.
62. Weziak-Bialowolska D. Differences in Gender Norms Between Countries: Are They Valid? The Issue of Measurement Invariance. European journal of population = Revue europeenne de demographie. 2015;31(1):51-76.
63. Macdermid JC, Graham ID. Knowledge Translation: Putting the “Practice” in Evidence-Based Practice. Hand Clinics. 2009;25(1):125-43.
64. Eccles MP, Hrisos S, Francis J, Kaner EF, Dickinson HO, Beyer F, et al. Do self-reported intentions predict clinicians' behaviour: a systematic review. Implementation Science. 2006;1(1).
65. Wakefield J, Herbert CP, Maclure M, Dormuth C, Wright JM, Legare J, et al. Commitment to change statements can predict actual change in practice. The Journal of continuing education in the health professions. 2003;23(2):81-93.
66. van Braak M, Visser M, Holtrop M, Statius Muller I, Bont J, van Dijk N. What motivates general practitioners to change practice behaviour? A qualitative study of audit and feedback group sessions in Dutch general practice. BMJ open. 2019;9(5):e025286.



Supplementary table 1: Distribution of the scores of intention to include sex and gender considerations in patient care in the clinical context of T2D and depression

	Parametric estimation*				**Non-parametric estimation†**		
	Innovation	Control	Mean difference (95% CI)	*P*Value‡	Innovation	Control	*P* Value£
No. of participants	49	78			49	78	
Total	5.65±0.19	5.19±0.15	-0.47 (-0.95; 0.01)	0.057	5.50 (5.00; 6.50)	5.50 (4.50; .00)	0.162
Age (years)							
< 44	5.68±0.25	5.30±0.18	-0.38 (-1.00; 0.24)	0.226	5.50 (5.00; 6.50)	5.50 (5.00; 6.50)	0.717
≥ 45	5.92±0.29	4.93±0.26	-0.99 (-1.78; -0.20)	**0.016**	6.00 (5.00; 6.50)	5.50 (3.50; 6.00)	**0.029**
Gender							
Men	5.79±0.45	4.79±0.34	-0.99 (-2.19; 0.20)	0.098	6.00 (5.00; 6.50)	5.25 (3.50; 6.00)	0.070
Women	5.78±0.21	5.24±0.17	-0.54 (-1.08; 0.00)	0.051	5.50 (5.00; 6.50)	5.50 (4.50; 6.50)	0.245
Language							
French	5.81±0.20	5.35±0.16	-0.46 (-0.97; 0.05)	0.073	6.00 (5.00; 6.50)	5.50 (4.50; 6.00)	0.133
Other	5.70±0.42	4.76±0.35	-0.94 (-2.05; 0.17)	0.096	5.50 (5.00; 6.50)	5.50 (4.50; 6.00)	0.346
Province of practice							
Quebec	5.85±0.20	5.43±0.15	-0.43 (-0.94; 0.08)	0.097	6.00 (5.00; 6.50)	5.50 (5.00; 6.50)	0.144
Ontario	5.83±0.43	4.89±0.43	-0.94 (-2.23; 0.34)	0.138	6.00 (5.00; 6.50)	5.00 (4.50; 6.00)	0.223
New Brunswick	5.36±0.73	4.00±0.64	-1.36 (-3.44; 0.72)	0.184	5.50 (5.00; 5.50)	4.00 (1.00; 6.00)	0.512
Environment of practice							

Urban	5.74±0.20	5.37±0.16	-0.37 (-0.88; 0.13)	0.143	5.50 (5.00; 6.50)	5.50 (5.00; 6.50)	0.486
Rural	6.38±0.87	4.45±0.55	-1.93 (-4.17; 0.32)	0.086	6.25 (6.00; 6.75)	5.25 (3.50; 6.00)	**0.018**

*Mean±standard deviation;
†Median (25th percentile; 75th percentile);
‡Derived from the general linear models;
£Derived from the Kruskal-Wallis (Wilcoxon) test

Supplementary table 2: Recommendations for improving the CPD training, based on barriers and facilitators, using the COM-B model, the Theoretical Domains Framework and the CPD-Reaction questionnaire

COM-B criteria	COM-B criteria subcategory	TDF domains linked to COM-B	Barriers and facilitators perceived by health professionals to including sex and gender considerations in their clinical practice	Psychosocial determinants of the CPD-Reaction questionnaire	Recommendations (COM-B Intervention function)
Opportunity					
	Social	Social influence	Health professionals assume the patient's gender based on his/her societal role (Barrier)	Social influence	In the CPD course, a clinical case vignette could demonstrate the integration of sex and gender considerations and reflect on the different social stigmas associated with gender (Modelling)
	Physical	Environmental context and resources	The patient's sex is routinely recorded in medical notes (Facilitator)		CPD training could expand on routine practices that already include sex and gender in clinical practice, example: recording sex, but going further by asking questions about perceived gender, sexual orientation (Training)
			The androcentric nature of the French language (the use of masculine generic language to refer to men and women, as well as other gender representations) (Barrier)		CPD training could give prompts/cues to demonstrate sex- and gender-sensitive medical language (e.g. revised forms, gender sensitive formulation of questions on sexuality and relationships) to promote equity in clinical practice (Environmental restructuring) The CPD training could encourage health professionals to self-monitor their use of gender inclusive language (Training/Enablement)
			The healthcare professional perceives that the language used by physicians towards a patient may be		CPD training could demonstrate sex- and gender-sensitive behaviours and patterns of speech through video animations of clinical visits between health professionals and their

			different according to sex and gender (Barrier)		patients, as well as showing various health professional and patient scenarios (Training)
Motivation					
	Reflective	Social and professional role and identity	The health professional reflects positively on his/her relationship with the patient (Facilitator)		
		Beliefs about capabilities	The health professional feels he/she can accurately observe the phenotype of the patient (Facilitator)	Beliefs about capabilities	Self-monitoring of behaviour to encourage health professionals to analyse how they record patient phenotypes: what do they take into consideration? Do they ask specific questions or is it strictly observational? (Enablement)
		Intentions	The health professional has the intention to change his/her therapeutic approach by considering the differences of gender (Facilitator)	Intention	Enable health professionals to change their behaviour by demonstrating strategies they have already undertaken to consider the sex of the patient during their therapeutic approaches (Modelling)
			The health professional does not have the intention to change his/her therapeutic approach by considering the differences of gender (Barrier)		Offer information about social consequences of not modifying their care to include sex and gender considerations (Education) Offer information about health consequences of not modifying their care to include sex and gender considerations (Education)
		Goals	The health professional does not perceive the integration of the concepts of sex and gender in clinical practice as a priority (Barrier)		Enable participants to engage in action planning to include sex and gender considerations in their clinical practice, as well as implementation intentions (Enablement) Enable participants to engage in specific goal setting on how

					they would include sex and gender considerations in their clinical practice (Goal setting)
		Beliefs about consequences	The health professional mentions that they would not change their therapeutic approach according to the patient's gender (Barrier)	Beliefs about consequences	Offer CPD content with credible sources about the health consequences of not modifying their care to include sex and gender considerations (Education) Demonstration of various techniques, shared decision making, cues and prompts that include sex and gender considerations in care (Modelling)
Capability					
	Psychological	Memory, Attention and Decision Processes	The health professional perceives that sex and gender are not systematic in the decision-making process (Barrier)		Offer specific training to create routine and habit formation that encourages the systematic inclusion of sex and gender considerations in the decision-making process (Training)
		Cognitive and interpersonal skills	The health professional does not assume the sex of the patient and acknowledges different treatment methods by gender (Facilitator)		
			The health professional acknowledges different clinical representation by gender (Facilitator)		
			The health professional assumed the gender of the patient when analyzing a clinical vignette (Barrier)		As part of skills training, the CPD training could demonstrate how to explore the different aspects of sex attribution, without assuming the sex of the patient (Training) Give specific instructions on how to explore the different aspects of sex attribution,

					without assuming the sex of the patient (Training) Offer feedback on outcome(s) of assuming the sex of the patient in a clinical case vignette (Training) Offer a practice/rehearsal period after receiving instructions on how to explore the different aspects of sex attribution, without assuming the sex of the patient (Training)
		Knowledge	The health professional recognizes the differences between sex and gender in scientific literature (Facilitator)		
			The health professional did not ask the gender of the patient when analyzing a clinical vignette (Barrier)		Include information on the possible clinical outcome(s) of assuming the wrong sex or gender of the patient (Education)
			The health professional is not aware of the concepts of sex and gender (Barrier)		Offer information about health consequences of not considering or confusing sex and gender terms (Education)

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1 (mixed methods)
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	7-8
	2b	Specific objectives or research questions for pilot trial	8
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	8
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	9-10
	4b	Settings and locations where the data were collected	9-10
	4c	How participants were identified and consented	9-10
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9-10-11
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	11-12
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	NA
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	NA
Sample size	7a	Rationale for numbers in the pilot trial	11
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	NA
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	NA
Allocation concealment	9	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	NA

mechanism			
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	10-11
	11b	If relevant, description of the similarity of interventions	10-11
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	12-13
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	14
	13b	For each group, losses and exclusions after randomisation, together with reasons	14
Recruitment	14a	Dates defining the periods of recruitment and follow-up	14
	14b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	14-15
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	14-15-16
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	15-16-17
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
	19a	If relevant, other important unintended consequences	NA
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	24-25
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	24
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	22-23-24
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	23-24
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	5
Protocol	24	Where the pilot trial protocol can be accessed, if available	NA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	27
	26	Ethical approval or approval by research review committee, confirmed with reference number	27

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.