# **BMJ Open** Chronic disease prevention and screening outcomes for patients with and without financial difficulty: a secondary analysis of the BETTER WISE cluster randomised controlled trial

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# ABSTRACT

**To cite:** Aubrey-Bassler K, Patel D, Fernandes C, *et al.* Chronic disease prevention and screening outcomes for patients with and without financial difficulty: a secondary analysis of the BETTER WISE cluster randomised controlled trial. *BMJ Open* 2024;**14**:e078938. doi:10.1136/ bmjopen-2023-078938

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (https://doi.org/10.1136/ bmjopen-2023-078938).

Received 16 August 2023 Accepted 18 March 2024

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**Objective** Building on Existing Tools To improve chronic disease pRevention and screening in primary care Wellness of cancer survivorS and patiEnts (BETTER WISE) was designed to assess the effectiveness of a cancer and chronic disease prevention and screening (CCDPS) programme. Here, we compare outcomes in participants living with and without financial difficulty. **Design** Secondary analysis of a cluster-randomised

**Design** Secondary analysis of a cluster-randomised controlled trial.

Setting Patients of 59 physicians from 13 clinics enrolled between September 2018 and August 2019. Participants 596 of 1005 trial participants who responded to a financial difficulty screening question at enrolment.

Intervention 1-hour CCDPS visit versus usual care. Outcome measures Eligibility for a possible 24 CCDPS actions was assessed at baseline and the primary outcome was the percentage of eligible items that were completed at 12-month follow-up. We also compared the change in response to the financial difficulty screening question between baseline and follow-up. Results 55 of 265 participants (20.7%) in the control group and 69 of 331 participants (20.8%) in the intervention group reported living with financial difficulty. The primary outcome was 29% (95% CI 26% to 33%) for intervention and 23% (95% CI 21% to 26%) for control participants without financial difficulty (p=0.01). Intervention and control participants with financial difficulty scored 28% (95% CI 24% to 32%) and 32% (95% CI 27% to 38%), respectively (p=0.14). In participants who responded to the financial difficulty guestion at both time points (n=302), there was a net decrease in the percentage of participants who reported financial difficulty between baseline (21%) and follow-up (12%, p<0.001) which was similar in the control and intervention groups. The response rate to this question was only 51% at followup.

**Conclusion** The BETTER intervention improved uptake of CCDPS manoeuvres in participants without financial difficulty, but not in those living with financial difficulty.

# STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Clinical trial, using a strong cluster randomised and usual-care-controlled design, which enrolled a large and diverse sample of 1005 participants and 59 physicians from 13 rural and urban practices across three Canadian provinces.
- $\Rightarrow$  Given the sensitivity of the question, the response rate to the financial difficulty screening question in this trial was reasonable (59%), resulting in 596 participants for the analyses reported here.
- ⇒ In the participants living with financial difficulty, there were imbalances between control and intervention groups in some covariates; however, results were adjusted for these covariates and the imbalance appears to favour the null hypothesis.
- ⇒ This study was designed and powered to determine the effectiveness of the intervention in all participants and may, therefore, be underpowered to assess effectiveness in the subgroups reported here.

Improving CCDPS for people living with financial difficulty may require a different clinical approach or that social determinants be addressed concurrently with clinical and lifestyle needs or both.

Trial registration number ISRCTN21333761.

## INTRODUCTION

Health systems around the world focus overwhelmingly on the management of chronic diseases rather than their prevention, in part because practitioners lack the tools and the time to adequately address topics such as behaviour modification.<sup>1</sup> The health sector focuses even less on the social determinants of health<sup>2</sup> despite analyses showing that socioeconomic factors are much more important than health system factors as determinants of health.<sup>3–6</sup> Other analyses demonstrate that increases in social spending have been associated with improved health outcomes, whereas increases in health spending have not.<sup>7</sup> These facts have led to increasing calls for action on the social determinants of health,<sup>8</sup> but progress in the health system has been slow and only a handful of programmes have been described.<sup>9–14</sup>

The BETTER (Building on Existing Tools To improvE chronic disease pRevention and screening in primary care) intervention is an evidence-based approach to comprehensively address primary prevention and screening of cancer and chronic diseases, with demonstrated effectiveness in randomised clinical trials and an implementation study.<sup>15–17</sup> The approach involves one-on-one prevention visits with patients at which they learn about their cancer and chronic disease prevention and screening (CCDPS) status and cancer and chronic disease risk, set specific, measurable, attainable, realistic, time-bound<sup>18</sup> goals for their health and receive information about resources in their community to help them meet their health goals. To date, the BETTER intervention has addressed lifestyle factors and referrals for disease screening tests but has not attempted to identify or address socioeconomic risk factors for chronic disease. We recently completed the BETTER WISE (BETTER for Wellness of cancer survlvorS and patiEnts) cluster randomised controlled trial (cRCT), which studied the original BETTER intervention supplemented with the addition of prostate, breast and colorectal cancer survivor surveillance. BETTER WISE also added questions to screen for financial difficulty and other social needs and referred participants with identified needs to appropriate resources. The primary results from BETTER WISE have now been published. In contrast to previous BETTER programme studies mentioned above,<sup>15–17</sup> the primary intention-to-treat (ITT) analyses, which did not consider financial difficulty, show that the effectiveness of the BETTER WISE intervention was not statistically significant, although per-protocol analyses of participants enrolled prior to the imposition of the COVID-19 restrictions showed a 21% improvement (p=0.001) in CCDPS compared with usual care.<sup>19</sup>

This paper reports the preplanned secondary analysis of BETTER WISE results stratified by participant responses to the financial difficulty screening question to assess whether the effectiveness of the intervention differed between patients living with and without financial difficulty. We also report on the association between participation in the BETTER WISE intervention and change in self-reported financial difficulty.

#### **METHODS**

The protocol,<sup>20</sup> preparatory work<sup>21</sup> and main results<sup>19</sup> for the BETTER WISE cRCT, as well as the results of the cancer survivor subgroup,<sup>22</sup> have previously been published, but the analyses documented here have not been reported elsewhere. Briefly, 59 physicians from 13 practices in 3 Canadian provinces were randomly assigned 1:1 to an immediate CCDPS arm or a control arm that received the same intervention after 1 year. Patients aged 40–65 from the participating practices were invited to enrol in the study. Outcomes were assessed in both groups at 12 months after randomisation, prior to the control group receiving the active intervention.

Although this was a preplanned secondary analysis, the specific details of the modelling, stratified by the financial difficulty screening question, were not mentioned in our published protocol as the focus on that paper was the primary outcome. As evidence of the preplanning, the published version of the protocol documents the incorporation of a screen for poverty.<sup>20</sup>

#### Intervention

The core component of this CCDPS intervention focuses on the primary prevention of chronic disease using referrals for recommended screening tests, lifestyle counselling and goal setting facilitated by a trained, nonphysician 'prevention practitioner', who held one-on-one prevention visits with patients. For BETTER WISE, the surveillance of breast, colorectal and prostate cancer survivors and a poverty screen were added to the original intervention. The question 'Do you ever have trouble making ends meet at the end of the month?' has been shown to identify people living below the poverty line with high sensitivity and reasonable specificity,<sup>11</sup> and was widely recommended for this purpose at the time BETTER WISE was designed.<sup>23</sup> Study participants who answered this question affirmatively were asked several follow-up questions to identify resources to which they could be referred.

The BETTER WISE baseline questionnaire asked participants about their medical history, family history and lifestyle factors. The questionnaire also included the Euro-Quol five-dimension quality of life instrument,<sup>24</sup> the two-item Patient Health Questionnaire<sup>25</sup> instrument to screen for depression and the two-item Generalised Anxiety Disorder<sup>26</sup> instrument to screen for anxiety. Additional tools used to deliver the BETTER WISE intervention are described elsewhere.<sup>27</sup>

#### **Outcomes**

The primary outcome for BETTER WISE was a composite index consisting of 24 CCDPS actions. We assessed participant eligibility for these actions at the baseline prevention visit and the number of eligible items served as the denominator for the composite index. For example, if breast, colorectal or cervical cancer screening had not been completed within the recommended time, or if diet, physical activity or alcohol use were not at recommended targets at the initial participant visit, these became items that a participant was eligible to improve on. The proportion of those items that were completed or improved at the follow-up assessment, approximately 12 months after the initial visit, became the numerator for the primary outcome.

We examined changes in response to the financial difficulty screening question as an additional outcome that was directly relevant to the research question addressed in the current paper. Because this outcome was not prespecified, results should be interpreted with caution. The study registration included two prespecified secondary outcomes which were reported in the main outcomes paper<sup>19</sup> but are not relevant to the current comparison and are, therefore, not reported here.

# **Statistical analysis**

We assessed the impact of the BETTER WISE intervention and financial difficulty adjusted for clustering within physicians using generalised estimating equation (GEE) regression models with a compound symmetric working correlation structure. Several options are available to account for the independence violation associated with the cluster sampling design, but we used GEE models because the study design and the number of clusters fit GEE requirements, and we were interested in a population-averaged interpretation of estimated regression coefficients.<sup>28</sup> We investigated the impacts of model selection on our results and determined that different models led to similar statistical inferences. A linear GEE method was used to model the impact of covariates on the composite outcome, whereas Poisson GEE models were used to model the impact of covariates on the count of the number of eligible and completed actions. Participant age, sex and province were included as covariates in all models. We also included an interaction term in the regression model to determine if the effect of the intervention differed between participants with and without financial difficulty. When we found that the interaction was statistically significant, we stratified the models by financial difficulty for the primary analyses. Other covariates were analysed in bivariate models and were included in the multivariate analyses if p<0.2, and variables were subject to backwards elimination from the multivariate models if their significance was  $\geq 0.2$ . To maintain consistency between the stratified models, variables were only eliminated if their p value was  $\geq 0.2$  in both models. McNemar's test was used to assess the change in the proportion of participants reporting financial difficulty at baseline and follow-up.

Study data were collected and managed using REDCap<sup>29</sup> electronic data capture tools hosted by the Women and Children's Health Research Institute at the University of Alberta. Verbal informed consent was obtained from all study participants prior to enrolment and written informed consent was obtained prior to participants' first prevention visit via mail or in person.

## Patient and public involvement

The BETTER WISE intervention was informed by the chronic care model<sup>30</sup> and previous research in this area, much of which included patient input. The patient perspective was represented by three individuals, one from each participating Canadian province, who did not

participate in the study but were involved in the development of the study protocol, knowledge creation and knowledge translation. One patient representative was involved in all aspects of BETTER WISE and as a member of the trial steering committee and is included as a coauthor on this paper (TW). Study personnel based outside of the clinic do not have access to participant identification or contact information and are thus unable to communicate results directly to participants. Results of the study have been communicated to each of the participating clinics and they are able to communicate results at their discretion.

# RESULTS

Patient recruitment into BETTER WISE began in January 2018, CCDPS baseline visits occurred between September 2018 and August 2019, and 12-month follow-up was completed by September 2020. An outline of study recruitment and exclusions, including the participants who responded to the financial difficulty screening question, is provided in figure 1. Participants who did not respond to this question at the baseline visit were excluded from this analysis. The 124 participants who reported living with financial difficulty responded to related follow-up questions as follows: 73 (59%) had submitted their most recent tax returns, 41 (33%) had children under 18 years (27 (66%) of whom received Canada Child Health Benefits), 3 (2%) received social assistance and 30 (24%) reported a disability (10 (33%) of whom received payments for their disability).

Table 1 outlines participant characteristics and table 2 documents the prevalence of chronic disease in participants living with and without financial difficulty. Interestingly, participants with a range of incomes including those with greater than \$C150000 per year reported living with financial difficulty, though the proportion was greater at lower incomes. Certain demographic characteristics such as male sex, older age and postsecondary education were also associated with a lower prevalence of financial difficulty in these descriptive analyses. The prevalence of smoking was higher in participants with financial difficulty and rates of chronic disease tended to be similar or higher, particularly obesity and diabetes. Within the participants living with financial difficulty, note that there were substantial differences between the control and intervention groups, particularly in education, marital status, income, smoking, alcohol use and housing. Furthermore, most of these differences suggest that the health status of the control group at baseline was greater than that of the intervention group, and these differences may help explain some of our results as discussed further below.

In multivariate adjusted analyses of the full study sample, the BETTER WISE intervention (p=0.01),



Figure 1 Study flow chart: eligibility, enrolment and follow-up for patients included in these analyses. CCDPS, cancer and chronic disease prevention and screening.

	No financial d	ifficulty	Financial diffi	culty
	Control (N=210)	Intervention (N=262)	Control (N=55)	Intervention (N=69)
Age-mean years±SD	55.1±6.7	55.0±7.1	53.1±6.9	52.9±6.6
Sex-female	118 (56.2)	167 (63.7)	40 (72.7)	47 (68.1)
Ethnic background—Caucasian	169 (80.5)	208 (79.4)	43 (78.2)	59 (85.5)
Canadian citizen by birth	184 (87.6)	222 (84.7)	49 (89.1)	57 (82.6)
≥1-year postsecondary education	157 (74.8)	208 (79.4)	36 (65.5)	52 (75.4)
Employment—FT or PT	150 (71.4)	193 (73.7)	42 (76.4)	51 (73.9)
Married or common-law	177 (84.3)	223 (85.1)	40 (72.7)	40 (58.0)
Total household income				
<\$C60 000	26 (12.4)	51 (19.5)	21 (38.2)	32 (46.4)
\$C60000-\$C99999	52 (24.8)	47 (17.9)	15 (27.3)	15 (21.7)
\$C100000-\$C149999	45 (21.4)	58 (22.1)	8 (14.5)	9 (13.0)
>\$C150 000	48 (22.9)	72 (27.5)	6 (10.9)	4 (5.8)
Current smoker	20 (9.5)	29 (11.1)	10 (18.2)	19 (27.5)
Smoking-mean pack-years±SD	18.1±12.5	15.5±16.6	12.7±9.4	18.7±16.5
Current alcohol consumption				
0 per week	28 (13.3)	31 (11.8)	11 (20.0)	10 (14.5)
1–6 per week	104 (49.5)	125 (47.7)	18 (32.7)	30 (43.5)
7–13 per week	22 (10.5)	30 (11.5)	5 (9.1)	7 (10.1)
≥14 per week	10 (4.8)	14 (5.3)	3 (5.5)	4 (5.8)
Binge alcohol consumption	13 (6.2)	19 (7.3)	3 (5.5)	6 (8.7)
Medication insurance	174 (82.9)	224 (85.5)	38 (69.1)	48 (69.6)
Worry about losing place to live				
Rarely	190 (90.5)	247 (94.3)	38 (69.1)	39 (56.5)
Sometimes	15 (7.1)	9 (3.4)	10 (18.2)	19 (27.5)
Very often	1 (0.5)	3 (1.1)	3 (5.5)	5 (7.2)
Always	1 (0.5)	0 (0.0)	4 (7.3)	6 (8.7)
Food security				
High	204 (97.1)	255 (97.3)	31 (56.4)	45 (65.2)
Low	5 (2.4)	6 (2.3)	21 (38.2)	18 (26.1)
Very low	0 (0.0)	1 (0.4)	3 (5.5)	5 (7.2)

Data are n (%) unless otherwise stated.

CAD, Canadian; educ, education; FT, full time; PT, part time.

financial difficulty (p=0.002) and the interaction between these two variables (p=0.01) were significantly associated with the primary outcome. The significance of this interaction term suggests that the effect of the intervention was different in participants living with and without financial difficulty, which was an anticipated result—we hypothesised that effectiveness would be lower or neutral in participants living with financial difficulty. We, therefore, conducted GEE analyses stratified by financial difficulty and report the outputs of those models in table 3. In the stratified models, the intervention was associated with the expected improvements to the primary outcome in participants without financial difficulty (intervention=29%, control=23%, p=0.01). In participants with financial difficulty, the difference between control (32%) and intervention (28%) was not statistically significant (p=0.14). However, note that the direction of the difference in participants living with financial difficulty (control outperforming intervention) is opposite to that in their counterparts without financial difficulty. Participant eligibility at the baseline visit and achievement at 12-month follow-up for each of the individual CCDPS actions are presented in online supplemental table 1 and the results of the multivariate analyses with the primary outcome as the

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	No financial di	fficulty	Financial diff	ficulty
	Control (N=210)	Intervention (N=262)	Control (N=55)	Intervention (N=69)
Self-reported diabetes	14 (6.7)	21 (8.0)	12 (21.8)	12 (17.4)
Body mass index—mean±SD	29.1±6.0	29.3±5.9	32.5±8.6	30.5±6.5
25.0–29.9	73 (34.8)	100 (38.2)	12 (21.8)	18 (26.1)
30–34.9	57 (27.1)	61 (23.3)	16 (29.1)	18 (26.1)
35–39.9	12 (5.7)	24 (9.2)	7 (12.7)	7 (10.1)
≥40	12 (5.7)	17 (6.5)	9 (16.4)	8 (11.6)
Obesity	81 (38.6)	102 (38.9)	32 (58.2)	33 (47.8)
CVD	16 (7.6)	23 (8.8)	4 (7.3)	9 (13.0)
Chronic kidney disease	5 (2.4)	5 (1.9)	1 (1.8)	1 (1.4)
COPD	0 (0.0)	9 (3.4)	1 (1.8)	3 (4.3)
Colorectal cancer	5 (2.4)	7 (2.7)	1 (1.8)	1 (1.4)
Breast cancer (women only; N=460)	15 (3.2)	19 (4.1)	0 (0.0)	4 (0.9)
Prostate cancer (men only; N=273)	8 (2.9)	6 (2.2)	0 (0.0)	0 (0.0)
Cervical cancer (women only; N=460)	3 (0.7)	4 (0.9)	0 (0.0)	6 (1.3)
EQ5D summary index—mean±SD	0.86±0.11	0.85±0.10	0.73±0.20	0.77±0.19
PHQ-2 score—mean±SD	0.57 (1.09)	0.69 (1.18)	1.55 (1.50)	1.39 (1.33)
Positive screen	11 (5.2)	17 (6.5)	14 (25.5)	9 (13.0)
GAD-2 score—mean±SD	0.89 (1.30)	0.90 (1.23)	1.67 (1.88)	1.72 (1.61)
Positive screen	17 (8.1)	22 (8.4)	15 (27.3)	15 (21.7)

Data are n (%) unless otherwise stated.

COPD, chronic obstructive pulmonary disease; CVD, cardiovascular disease; EQ-5D, Euro-Quol 5-Dimension; GAD-2, Generalised Anxiety Disorder 2-item screening tool; PHQ-2, Patient Health Questionnaire-2.

dependent variable are presented in online supplemental table 2.

Table 4 documents responses to the financial difficulty screening question and how those responses changed between baseline and approximately 12 months postintervention. Of the 596 participants in this study sample, 302 (51%) responded to the financial difficulty screening question at follow-up, including 148 of 265 (56%) in the control group and 154 of 302 (51%) in the intervention group. There was a statistically significant decrease in the proportion of participants reporting financial difficulty

difficulty and randomisation group									
		Full	No financial difficulty			Financial difficulty			
		population (N=596)	Control (N=210)	Intervention (N=262)	P Control Intervention value* (N=55) (N=69)		Intervention (N=69)	P value*	
Eligible action	s	8.53±2.63	8.60±2.62	8.18±2.62	0.28	9.07±2.68	9.16±2.49	0.74	
Actions met		2.37±2.02	2.15±1.85	2.39±2.09	0.52	2.96±1.98	2.51±2.23	0.42	
Composite score (%)	Unadjusted	28±22	24±19	29±24	0.22	34±21	27±24	0.31	
	Adjusted	-	23 (21–26)	29 (26-33)	0.01	32 (27–38)	28 (24–32)	0.14	

 Table 3
 Study outcomes – prevention and screening eligibility and achievement at 12 months postintervention by financial difficulty and randomisation group

Data are mean±SD except for adjusted composite score which are mean (95% CI). Adjusted composite scores and CIs are estimated for an average study participant from the results of GEE models.

Eligible actions are the number of cancer and chronic disease prevention and screening actions that were out of date or not on target at the baseline visit; Completed actions are the number of eligible actions that were addressed or improved on at the follow-up visit; Composite score is the ratio of completed actions to eligible actions (the primary outcome).

\*P values are from GEE models for the comparison of intervention to control within each financial difficulty group. Eligible and completed actions were assessed in Poisson models and composite scores were assessed in linear GEE models.

GEE, generalised estimating equation.

 Table 4
 Change in self-reported financial difficulty between baseline and 12-month follow-up overall and by experimental group

•							
		Financial difficulty at 12-month follow-up					
		Full population (n=302) <sup>1</sup>		Intervention (n=154) <sup>2</sup>		Control (n=148) <sup>3</sup>	
		No	Yes	No	Yes	No	Yes
Financial difficulty at baseline	No	232	8	123	3	109	5
	Yes	34	28	17	11	17	17

Data are n. <sup>1</sup>p<0.001, <sup>2</sup>p=0.004, <sup>3</sup>p=0.019 by McNemar's test.

Table 4 includes only those participants who responded to the screening question at both the baseline and follow-up time points. Interpretation is as follows: For the full population, of the 240 (232+8) patients who reported no financial difficulty at baseline, 8 reported financial difficulty at 12-month follow-up. Of the 62 (34+28) patients who reported financial difficulty at baseline, 28 reported financial difficulty at 12-month follow-up. There was a net decrease in the number of people reporting financial difficulty from 62 (34+28) to 36 (28+8).

in both the intervention (21% at baseline vs 9% at follow-up, p=0.004) and control groups (21% at baseline vs 15% at follow-up, p=0.019).

## DISCUSSION

In the current paper, we sought to compare the effectiveness of the BETTER WISE chronic disease prevention and screening intervention in patients living with and without financial difficulty. The main ITT analyses show that the effectiveness of the BETTER WISE intervention was not statistically significant, although per-protocol analyses of participants who completed follow-up prior to the imposition of the COVID-19 restrictions showed a 21% improvement (p=0.001) in CCDPS compared with usual care.<sup>19</sup> Given several previous studies which have demonstrated the clear effectiveness of BETTER and its variants, <sup>161722</sup> we completed the secondary analyses reported here to better understand how the intervention impacted the health outcomes of participants experiencing financial difficulty. The secondary analysis of BETTER WISE ITT data reported here demonstrates that the intervention does appear to be effective in participants without financial difficulty, but not in those living with financial difficulty. Although it is possible that our study was underpowered to detect a difference in this smaller subgroup, we did not observe a trend that would be expected if inadequate power was the explanation for this lack of significance.

Intervention participants with and without financial difficulty both achieved 28%–29% of the CCDPS actions they were eligible for, vs 23% in the control/no financial difficulty subgroup (table 3). Surprisingly, control participants with financial difficulty achieved the highest primary outcome of all the groups (32%). Although this difference is not statistically significant and, therefore, plausibly due to chance, it is possible that it can in part be attributed to variability in the distribution of covariates between control and intervention in participants living with financial difficulty. Most of the measured covariates favour the control group (table 1). For example, the proportions of participants who are women, Canadian citizens, employed, married and non-smokers are all

higher in the control patients, and all of these factors are generally associated with a higher uptake of CCDPS.<sup>31–33</sup> The number of participants with financial difficulty was comparatively low (n=124) and randomisation occurred at the level of the physician rather than the participant, both of which may contribute to covariate imbalance. Although we adjusted our analyses for these covariates, important unmeasured covariates may also have varied in a similar direction. In support of this hypothesis, several covariates appeared to exert different or even opposite effects in the stratified multivariate models (see online supplemental table 2).

One additional possible explanation for these unusual findings relates to the COVID-19 pandemic. Approximately 55% of BETTER WISE participants received their 12-month follow-up visit after the beginning of the pandemic, during which access to health services, particularly non-urgent preventative services and screening tests, was heavily restricted. A number of these services and tests are included as individual components of the BETTER WISE composite index primary outcome. Clinicians who participated in our study have told us that they proactively contacted disadvantaged patients to update their screening practices when services reopened. Although we did not hear this specifically, clinic staff may have assumed that BETTER participants did not require this outreach. Regardless of the explanation, we will be monitoring this issue closely in future iterations of BETTER given the possible health equity implications.

We were encouraged that the financial situation of many study participants appeared to improve over the course of this study (see table 4). Unfortunately, almost half of the participants did not answer the financial difficulty screening question at follow-up, but the proportion of non-responders was virtually equal between individuals with and without financial difficulty at baseline. Although it is tempting to conclude that our intervention translated into improvements in financial situation, findings for the control group were similar, suggesting that external factors such as government benefits or reduced spending during the pandemic may help explain these results. Given other analyses demonstrating that the financial stability of Canadians either changed relatively little or deteriorated over the course of the pandemic,<sup>34 35</sup> and the low response rate on this question in our study, these results should not be considered representative.

Inequity in health status across societal groups has long been known<sup>3 36</sup> and differences in access to healthcare is likely a causal mechanism.<sup>37 38</sup> There are many other factors that contribute to health inequity but these are much more complex and less well understood.<sup>39</sup> While there are differences in rates of adverse health behaviours across socioeconomic groups that explains some of the variability in health status, studies show that health inequities persist even after adjusting for behavioural differences.<sup>36</sup> Interestingly, despite significant research in the area of health inequity, we were unable to find any documentation of differences in effectiveness of health services associated with social determinants, similar to our results here. If replicated elsewhere, this issue will be important to consider when decisions about clinical services are made based on the findings from research, given that research participants tend to be healthier and come from more advantaged social circumstances.<sup>40</sup>

This study has several limitations to consider. The question used to screen for financial difficulty in BETTER WISE has previously been used to identify people living below the poverty line<sup>11 23</sup>; however, it has not been extensively studied and very little work on validation for this purpose has been completed. Nonetheless, we expected that participants responding affirmatively to this question would have substantially greater differences in their determinants of health than what we observed. For example, 46% of participants in our sample living with financial difficulty reported annual household incomes greater than \$C60000 per year, 8% reported incomes greater than \$C150 000, and 71% reported at least some postsecondary education. Thus, these participants would not be considered significantly disadvantaged by usual measures. Given that people who agree to take part in health research tend to be healthier than the general population,<sup>40</sup> our results may also be subject to a selection bias, but this bias seems most likely to underestimate differences in effectiveness associated with financial difficulty. Admittedly, the impact of selection bias in our study population is difficult to estimate given the likely complex interplay between self-reported financial difficulty, research participation, and the health behaviours and utilisation of disease screening tests that form the composite outcome used in our study. Additional limitations of this study are discussed above.

This paper adds to a small body of literature that describes and studies health system interventions that address the social determinants of health.<sup>9-14</sup> Each of these papers describes tool development or examines the feasibility or acceptability of introducing social determinants screening programmes, but no studies to date have examined intervention effectiveness. Given widening gaps in health equity and diminishing returns in population

health within the traditional health system, this would seem like an important area for future research.

## CONCLUSIONS

The prespecified ITT analyses from the BETTER WISE trial, which did not consider financial difficulty as a covariate, did not demonstrate an improvement in CCDPS outcomes for patients who received the BETTER WISE intervention, although an analysis of patients enrolled prior to the COVID-19 pandemic did show the expected benefits.<sup>19</sup> The secondary analyses reported here demonstrate that BETTER WISE did improve CCDPS uptake in participants living without financial difficulty but not in those with financial difficulty. Improving CCDPS for people living with financial difficulty may require a different clinical approach or that social determinants be addressed concurrently with clinical and lifestyle needs, or both.

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Acknowledgements The authors wish to acknowledge the Prevention Practitioners who worked on BETTER WISE (A. Browne, L. Coughlin, S. French, D. Gallant, J. Gheseger, V. Hans, M. Lajeunesse, M. Larsen, K. Lilly, S. Moshiri, M. Rathnavalu, S. Sohanpal, T. Stainbrook, L. Weatherill, L. Wong and J. Zakrzewski) and the site leads for each participating clinic (Drs. B. Awakan, L. Barnes, A. Bencivenga, T. Burton, F. Dewet, K. Forse, N. Hans, A. Jorgensen, B. Mangat, L. McLeod, S. Newbery, C. Nichol, A. Pasha, K. Qasha and W. Tink).

**Collaborators** The authors wish to acknowledge the Prevention Practitioners who worked on BETTER WISE (A. Browne, L. Coughlin, S. French, D. Gallant, J. Gheseger, V. Hans, M. Lajeunesse, M. Larsen, K. Lilly, S. Moshiri, M. Rathnavalu, S. Sohanpal, T. Stainbrook, L. Weatherill, L. Wong and J. Zakrzewski) and the site leads for each participating clinic (Drs. B. Awakan, L. Barnes, A. Bencivenga, T. Burton, F. Dewet, K. Forse, N. Hans, A. Jorgensen, B. Mangat, L. McLeod, S. Newbery, C. Nichol, A. Pasha, K. Qasha and W. Tink).

**Contributors** KA-B, CF, AKL, DC-S and DPM were involved in all aspects of this work from study conception and design to acquisition, analysis and interpretation of data, to writing and/or revision of the manuscript. DP was involved in analysis and interpretation of the data and wrote the first draft of the manuscript. CM and RM were involved in conception, design and data analysis and interpretation. TW, ADP, MS-B, KM and EG were involved in conception, design and data interpretation. EG also conceived the BETTER intervention. DPM was the overall lead for the BETTER

WISE project. All authors have been involved in drafting and/or critically revising the manuscript, have given their approval of the published version and agreed to be accountable for the accuracy and integrity of the work. KA-B is the guarantor and takes full responsibility for the finished work.

**Funding** This work was supported by a Cancer Prevention Research Opportunity (CPRO) award #201500833 provided by Alberta Innovates.

**Disclaimer** The opinions, results and conclusions reported here are those of the authors and do not necessarily represent the views of the funders. No endorsement by Alberta Innovates is intended or should be inferred.

**Competing interests** DPM, EG, AKL and CF are directors of a Canadian not-for-profit organisation, The BETTER Institute, which provides training and implementation support to practices, organisations and communities interested in adopting or adapting the BETTER approach. There are no other competing interests to report.

**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and this study received ethics approval from the University of Alberta's Health Research Ethics Board (Pro00067811 and Pro00069064), St. Michael's Hospital Research Ethics Board (#17-050 and 17-248), Markham Stoufville Hospital Research Ethics Board (no file number assigned) and the Newfoundland and Labrador Health Research Ethics Board (#2017.027, 2017.027B, 2017.027C, 2017.027D and 2017.284). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request. The datasets generated during and/or analysed during the BETTER WISE study will not be made publicly available due to planned analyses and publications but are available from the senior author (DPM) on reasonable request.

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