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Self-Care Tools to Treat Depressive Symptoms in Older Adults with Ocular

Diseases: A Randomized Controlled Clinical Trial

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Abstract

Purpose: Depression is a common problem in people with age-related macular degeneration (AMD) and diabetic retinopathy (DR). Antidepressants and psychotherapy are often underutilized. Our goal was to determine if self-care tools plus limited telephone support could reduce depressive symptoms.

Methods: A single-blind randomized controlled clinical trial was conducted at Maisonneuve-Rosemont Hospital in Montreal, Canada. All eligible patients were invited to participate in the trial. To be eligible, participants must have had either late stage AMD or DR, at least mild depressive symptoms, and visual acuity better than 20/200 in their better eye. Half were randomized to the intervention arm and half to delayed intervention/usual care. The intervention consisted of large print written and audio tools incorporating cognitive-behavioral principles plus three 10-minute telephone calls from a coach. Eight-week follow-up data were collected by telephone. The primary outcome was the 8-week change in depressive symptoms as measured by the Patient Health Questionnaire (PHQ-9).

Results: Eighty participants, aged 50 years and older, were recruited while 10 were lost to follow-up (12.5%) giving 70 with complete data, 35 in each group. The mean baseline PHQ-9 score was 9.5 out of 27 (SD=3.9) indicating moderate depressive symptoms. The average decrease in PHQ-9 scores over the 8 weeks was 4.9 (SD=4.2) in the intervention group and 3.2 (SD=4.6) in the usual care group, a 1.7 point difference (P=0.104). After adjusting for baseline imbalances in visual acuity,

antidepressant use, and participation in psychotherapy, the difference increased from 1.7 to 2.3 and became statistically significant (p=0.037). Sixty percent of those in the intervention group reported having used the tools at the end of the study.

Conclusions: Self-care tools plus telephone coaching led to a small improvement in depressive symptoms in patients with age-related eye disease. Additional research into the best way to support depressed patients with age-related eye disease is necessary.

Key Words: Depressive symptoms, Eye disease, Self-care tools, Randomized Controlled Trial

Résumé

Objectif: La dépression est un problème fréquent chez les personnes atteintes de dégénérescence maculaire liée à l'âge (DMLA) et de rétinopathie diabétique (RD). Les antidépresseurs et les thérapies psychologiques sont souvent sous utilisés. Notre objectif était de déterminer si les outils d'auto-soins associés au support téléphonique limité pouvaient réduire les symptômes dépressifs.

Méthodes: Un essai clinique randomisé à simple insu a été mené à l'Hôpital Maisonneuve Rosemont, Canada. Tous les patients éligibles étaient invités à participer à l'essai. Pour être éligibles, les participants devaient 1) avoir un diagnostic de DMLA avancée ou de RD, 2) au moins des symptômes dépressifs moyens et 3) une acuité visuelle meilleure que 20/200 dans leur meilleur œil. Une moitié des participants était randomisée au bras d'intervention et l'autre moitié à l'intervention retardée/traitement usuel.

L'intervention était composée d'outils audio et écrits en gros caractères, incluant des principes cognitifs comportementaux plus trois appels téléphoniques d'un coach d'une durée de 10 minutes chacun. Les données de suivi étaient collectées huit semaines plus tard, par téléphone. L'issu primaire était le changement de symptômes dépressifs à huit semaines, mesuré par le questionnaire sur la santé du patient, PHQ-9.

Résultats: Quatre-vingts participants, âgés de 50 ans et plus ont été recrutés, dont 70 ayant des données complètes et 10 perdus de vue (12.5%). Le score moyen du

PHQ-9 à l'inclusion était de 9.5 (SD=3.9) indiquant des symptômes dépressifs modérés. La réduction moyenne du score de PHQ-9 au terme du suivi était de 4.9 (SD=4.2) dans le groupe d'intervention et de 3.2 (SD=4.6) dans le groupe de traitement usuel, soit une différence intergroupe de 1.7 point (p=0.104). Après avoir contrôlé pour les disparités observées à l'inclusion notamment pour l'acuité visuel, l'utilisation des antidépresseurs et la participation à la psychothérapie, cette différence est passée de 1.7 à 2.3 et est devenue statistiquement significative (p=0.037). Soixante pourcent des participants du groupe d'intervention ont rapporté avoir utilisé les outils d'auto-soins au terme de l'étude ou de l'exploitation des données

Conclusion: Les outils d'auto-soins accompagnés de support téléphonique conduisent à une petite amélioration des symptômes dépressifs chez les patients atteints de pathologies oculaires liées à l'âge. Des recherches additionnelles ciblant les meilleures stratégies pour soutenir les patients déprimés atteints de maladies oculaires liées à l'âge sont nécessaires.

Mots-clés: symptômes dépressifs, maladie oculaires, outils d'auto-soins, Essai randomisé contrôlé

Table of Contents

List of tables

List of figures

List of abbreviations

AIDS   Acquired Immune Deficiency Syndrome

AMD   Age related Macular Degeneration

ART   Antiretroviral Treatment

BOMC   Blessed Orientation Memory –Concentration

CBT   Cognitive Behavioral Therapy

CD   Compact Disc

CDC   Centers for Disease Control and Prevention

CI   Confidence Interval

CONSORT   Consolidated Standards of Reporting Trials

COPD   Chronic Obstructive Pulmonary Disease

DALY   Disability Adjusted Life Years

DR   Diabetic Retinopathy

DVD   Digital Versatile Disc

GAD   Generalized Anxiety Disorder

GDS-15   Geriatric Depression Scale

HIV   Human Immunodeficiency Virus

HMR   Hôpital Maisonneuve-Rosemont

HR   Hazard Ratio

IQR   Interquartile Range

LogMAR   Log Minimum Angle of Resolution

LSA   Life Space Assessment

OD   Odds Ratio

p	p-value
PHQ-9	Patient Health Questionnaire
PST	Problem solving treatment
RCT	Randomized Controlled Trial
SD	Standard Deviation
US	United States
WHO	World Health Organization

Dedication

To Georgette, my sweet mother, for her love and continuous support

Acknowledgements

Chapter 1: Introduction

1.1 The burden of depression

Depression is a major public health concern worldwide. Also known as major depressive disorder or clinical depression, depression is a mental illness affecting not only the mind but the body as a whole.(1) It refers to "a common mental disorder characterized by sadness, loss of interest or pleasure, feelings of guilt or low self-worth, disturbed sleep or appetite, feelings of tiredness and poor concentration". (2) The disease is one of the major causes of disability in the world.(3) Approximately 350 million people, predominantly women, are diagnosed with depressive symptoms around the world.(3) According to World Health Organization (WHO) estimates, it is one of the ten leading causes of disability adjusted life years (DALY) globally. If serious preventive measures are not taken to reduce the burden of the disease, depression could be among the top three causes of DALY's by 2030.(3)

In Canada, more than 2 million people are diagnosed with a mood disorder, one-third of them men. (4) Hospitalization for mood disorder is one and a half times more frequent in women than in men (5) and about 11% of men and 16% of women in Canada will experience major depression in the course of their lives. (6) Using administrative data from three large Canadian employers, 25% of short-term disability claims were due to a nervous or mental disorder, 76% of which were depression-related. (7) The Canadian government spends approximately $51 billion dollars each

year for the treatment of the disease, specifically for primary care visits, hospitalizations, and medication. (8, 9)

1.2 Risk factors for depression

Some risk factors for depression have been identified. These include biological, genetic, socio-demographic, psychological, behavioral, and medical factors. (2, 10)

1.2.1 Biological Factors

Research findings indicate that insufficient levels of neurotransmitters or an imbalance of brain chemicals (e.g., dopamine, serotonin, and norepinephrine) in some people might trigger depressive symptoms. (11, 12) Also, as a result of hormonal changes, some women may feel depressed after giving birth (13, 14) or at menopause. (15, 16) Some people experience depressive symptoms in the winter (seasonal affective disorder), possibly due to a lack of sunlight and vitamin D deficiency. (17-19)

1.2.2 Genetic Factors

Genetic factors play an important role in the aetiology of major depression as twin studies indicate a heritability of 40%-70% (20-22). Moreover, individuals with a family history of depression have an increased risk of suffering from depression compared to those with no immediate family member diagnosed with depressive symptoms. For example, a recent study revealed that individuals with an immediate family member diagnosed with depression are 2.8-10 times more at risk of developing depression. (23) However, no genes have yet been consistently identified.

1.2.3 Demographic Factors

Female gender is a risk factor for depression. Many studies have revealed a higher rate of depressive symptoms in women compared to men.(24) Age is also associated with depression as studies have revealed a higher prevalence of major depression among older adults.(25, 26) Moreover, marital status is a risk factor as well: widowed, divorced and separated individuals tend to be diagnosed with depressive symptoms more frequently compare to married people or people who have never been married. (24, 27) Furthermore, unemployed people and people with a relatively low annual income are more depressed compared to those making higher wages. (28, 29) Also, the disease tends to be more likely among urban residents versus rural residents. (30, 31)

Finally, some studies reported an association between race and major depression, especially among minority ethnic groups in the United States. Dunlop et al, in a study among preretirement Americans aged 54 to 65 years, indicated that African-Americans and Hispanics had an increased risk of being depressed compared to Whites, OR = 1.16 (95% CI 0.93-1.44) and OR=1.44 (95% CI 1.02-2.04) respectively (32). No major difference in depression rates has been observed among racial groups in Canada. However, a study carried out by Zheng and colleagues found a relatively better mental health condition among Chinese, Asian and black Canadians compared to white English Canadians and that the mental health status of other racial or ethnic groups were similar to that of white English Canadians. (33)

1.2.4 Psychological and Social Factors

People who experienced traumatic events during childhood might be more at risk of being depressed. For example, those who experienced sexual, physical or emotional abuse, who lost their parent or experienced parental divorce during this period, are more likely to be depressed.(34-37) Likewise, individuals who experienced negative life events such as divorce or loss of a loved one are at a higher risk of depression (38). Lack of social support also appears to be a risk factor. (31, 39, 40)

1.2.5 Medical Factors

Research has shown that some conditions are strongly associated with depression, namely hormonal imbalances, chronic viral infections, chronic pain, bone and connective tissue disease, neurological disease, respiratory disease, gastro-intestinal disease, AIDS, cancer, heart disease, thyroid disorders, and eye disease (41-46). Similarly, medications may cause depressive symptoms. These include but are not limited to analgesic medications like Demerol and Percocet, contraceptives, acne and antihypertensive medication.(47, 48)

1.2.6 Unhealthy behaviors

Research findings have also revealed that some unhealthy behaviors are associated with depression. For example, alcohol and tobacco consumption seem to be related in a dynamic, bidirectional relationship with depressive symptoms (49, 50). Physical inactivity is also a risk factor (51) (52). People who do not exercise regularly

or who have limited physical activity are at a higher risk of being depressed. Likewise, poor sleep, less than 7 to 9 hours of sleep per night seems to be associated with depression (53-55). A cross sectional study carried out by Coulombe and other researchers indicated that sleep disturbances were strongly associated with depression (56). Conversely, sleep problems have been reported as a consequence of depression in some individuals (57, 58).

1.3 Consequences of depression

Depression can increase the risk of other chronic mental illnesses like bipolar disorder, generalized anxiety disorder and obsessive-compulsive disorder.(59-61) Second, depression may impair interpersonal relationships of people affected. Individuals suffering from depression tend to isolate themselves from peers; family or colleagues and this may affect their relationship with others. (62-64) Third, depression has been pointed out as one of the major risk factors of suicide (65). The Centers for Disease Control and Prevention (CDC) classified suicide as the 10th leading cause of death among all age groups in the US in 2012 (66, 67). Fourth, depression is associated with worse life space, which is a measure of the spatial extent of a person over the last month. (68) Fifth, depression is associated with loss of productivity. Untreated depression was reported as having an impact on work and academic productivity.(69, 70) Dewa *et al*. carried out a study on depressive episodes and productivity among Canadian workers and found that untreated depressive symptoms have a highly negative impact on productivity.(71). For example, they found that the productivity loss of an organization where no one has access to treatment is five times that of an organization with access to depression related treatment.

Finally, depression is associated with an increased risk of death (72, 73). It is associated with mortality from heart disease, respiratory illness, cardiovascular disease, accidents, diabetes, nephritis, influenza, Alzheimer's, septicemia, Parkinson's and hypertension (45, 73-76). A meta-analysis carried out by Fan and colleagues in 2014 indicated that patients with major depression were at increased risk of all-cause mortality compared to non-depressive patients (HR = 1.98, 95% CI 1.23-3.19). (45)

1.4 Ocular diseases and depression in older populations

Visual impairment is a serious concern for people aged 65 years and older.(77-79) The prevalence of depression in older adults with visual impairment varies from 7 to 39% for clinical depression and 29 to 43 % for depressive symptoms. (77, 80) Many studies indicated that depression is strongly associated with ocular diseases. (44, 81-86)

In a recent cross-sectional study conducted in 2012, Popescu and colleagues (81) investigated the relationship between age related eye diseases and depression using the Geriatric Depression Scale (GDS-15). Three hundred and fifteen patients with age-related macular degeneration (AMD), Fuchs' corneal dystrophy, or glaucoma were compared to 88 people with no significant vision loss. The prevalence rate of depressive symptoms ranged between 29-39% in the groups with eye disease compared to only 8% in the group without eye disease (P<0.05). No changes were observed after adjustment for demographic, medical, and social factors. Furthermore, this research reported that limitations in life space and activity limitations due to a fear of falling mediated these relationships indicating that interventions that can help

people with eye disease to expand their mobility and maintain their activities may help to decrease the burden of depression in this population (81).

Likewise, Casten et al, in summarizing research findings on depression and age-related macular degeneration found a depression prevalence of about 30 % among AMD patients and revealed that depression is a major cause of disability among older adults(82). Furthermore, a recent cross-sectional study on depression and mood indicators in glaucoma patients found that patients who reported worse visual function were more likely to be depressed.(83)

Also, a prospective cohort study conducted by Sieu and colleagues on the association between depression and diabetic retinopathy suggested that diabetic patients with higher PHQ-9 depression scores have a significantly higher risk of developing diabetic retinopathy (OR=1.02; 95% CI; 1.00-1.05).(87). A study carried out in China among older adults with type 2 diabetes reported a high depression rate (35.7%). They did not have a control group but this rate is much higher than what is generally found in older adults .(88)

1.5 Treatments for depression

Psychotherapy and pharmacotherapy are two known treatment options available for depression. (3) Psychotherapy refers to psychological methods of treatment: "*a treatment technique for certain forms of mental disorders relying principally on talk/conversation between the mental health professional and the patient*" (89, 90) whereas pharmacology deals with the use of medication to treat the disease. The impact of pharmacotherapy or psychotherapy in depression treatment among children, adolescents, adults and elderly has been widely explored.(91, 92)

1.5.1 Combined pharmacotherapy and psychotherapy

While some studies have focused exclusively on the impact of pharmacotherapy (92, 93) or psychotherapy (94, 95) on depressive symptoms, several studies have examined the use of both treatment methods on the reduction of depressive symptoms and argued that combined therapies are much more effective than monotherapy (psychotherapy or pharmacotherapy alone).

Meta-analyses carried out on the topic revealed that both treatments have similar success rates, while emphasizing that psychotherapy may be more effective over the long-term. (96) In a meta-analysis, Cuijpers *et al.* investigated the effect of psychotherapy on pharmacotherapy treatment to reduce depressive disorders in adult patients. The result of the study revealed that psychotherapy has an added value compared to pharmacotherapy alone in depression treatment.(89)

Gerson and colleagues conducted a meta-analysis on published data comparing treatment rate response and tolerability of pharmacological and psychological treatments for depression among older adults aged 55 years and above. The result of the study did not indicate any significant difference in the response rates between the different types of treatment. (80) Finally, another meta-analysis looked at the effectiveness of psychotherapy compared to pharmacotherapy in older depressed patients. Only studies based on pharmacotherapeutic or psychotherapeutic interventions versus control (placebo or waiting list) were included in the analysis. The findings indicated that the effectiveness of both treatments were similar regarding the improvement of depression symptoms in this population. (81)

1.6 Limitations of current treatments

Despite the existence of pharmacological and psychological therapies, many depressed people remain undiagnosed and do not receive treatment. Of those who do receive treatment, side effects result in high rates of discontinuation of antidepressants as 50% of new users discontinued within 6 months in a group of over 90,000 Australian veterans.(97) Research indicates that if given the preference, adults with depression prefer psychotherapy to antidepressants by a 2:1 ratio (CI, 1.6 to 2.7, p=. 001) (98) A study found preference to be an important contributor to treatment success as those who had higher preference scores for psychotherapy compared to antidepressants were more likely to drop out of treatment in a trial of 100 patients with major depressive disorder (99). However, psychotherapy is often expensive in the private system and there are long waits in the public system as it is provided at no cost and there are often not enough therapists to meet demand. Psychotherapy in the private healthcare system is expensive; wait times in the public system can be very long. As an example, an hour-long session in the private services varies from 50 to 240 Canadians dollars and is only covered by some private insurance plans (100, 101).

Alternative strategies for delivering treatment to adults with depression are needed, particularly for vulnerable and often isolated populations like older adults with vision problems. Therefore, we propose to investigate the use of self-care tools, which will allow people with depression to take care of themselves in the privacy of their own home.

1.7 Specific objectives and hypotheses

The main objective of this study is to determine the short-term effect of a self-care intervention on depression in patients with age-related ocular diseases, namely age-related macular degeneration and diabetic retinopathy. We hypothesized that the use of self-care tools would reduce depressive symptoms in these patients. The secondary objectives will be to 1) examine the effects of the intervention on anxiety symptoms, life space, and self-efficacy, 2) examine whether the effects of the intervention vary by patient characteristics such as socio-demographic factors, physical health, severity of vision loss, eye disease, and level of self-efficacy.

1.8 Significance of the study

This study is the first to investigate self-care tools in patients with age-related eye disease. The research findings could result in the availability of a low-cost, efficacious intervention that could be widely offered within ophthalmology or optometry clinics and low vision rehabilitation agencies to reduce the burden of depression in those with age-related eye disease. It may reduce depressive symptoms by itself or it may also encourage the patient to speak to his or her physician and discuss other treatment options for depression. If patients with age-related eye disease have their mental health under control, they will likely be better able to comply with their prescribed treatment regimens leading to better vision outcomes.

Chapter 2: Literature review on self-management

2.1 What is self-management?

Self-management, also known as patient empowerment, or self-care, refers to an individual's ability to manage the symptoms, treatment, physical, psychosocial, and lifestyle changes inherent in living with a chronic condition. (102) It could also be considered as "*a treatment that combines biological, psychological and social intervention techniques, with a goal of maximal functioning of regulatory processes.*" (103).

There are three main tasks associated with self-management. These include medical management, emotional management and role management (104-106). Medical management refers to activities like taking medication, adhering to a special diet or using an inhaler. The second task involves managing emotions like anger, fear, frustration, and depression that can occur when faced with a chronic disease. The last task deals with changing, creating or maintaining new behaviors or life roles (104). Moreover, self-management education provides patients with 6 types of skills, namely:

- Problem solving: how to generate possible solutions to circumstances they are facing

- Decision-making provide them with useful knowledge in order to take action and improve their situation

11

- Resource utilisation teach patients how to use the available resources

- Partnership with health care providers trains and prepares patients how to communicate efficiently with their health care provider.

- Action planning: provides patient with information on how to take action in order to change a particular behavior

- Self-tailoring or self-efficacy gives patients the confidence to carry out activities necessary to reach a desired goal

Research indicates that patients can change the progression of their disease and become able to handle their own health if given proper training and support. (104,105) This implies involving patients in the management of their disease including the medical, behavioural, and emotional aspects.

In general, self-management interventions are defined as requiring less than three hours of professional support and can be delivered in person, by telephone, over the internet, in a one-on-one or group session (107). This treatment strategy has been widely used in healthcare settings, particularly in those with chronic disease.

2.2 Self-management and chronic diseases

The study of self-management interventions for some chronic diseases has been widely explored. Much work has been done in the fields of cardiovascular disease, pain, and HIV. For example, a systematic review was recently conducted to examine the effectiveness of mobile health wireless device (mHealth) interventions on behavioural lifestyle changes and medication adherence for cardiovascular disease

self-management using data from seven clinical trials. (108) Three trials showed that text messaging could improve medication adherence and two trials showed that text messaging could improve physical activity but no significant results were seen on dietary behavior or smoking cessation. This systematic review suggested that mHealth was effective in changing certain lifestyle behaviours among a cardiovascular disease population.

In the field of podiatry, a randomized clinical trial was carried out to explore the clinical and cost effectiveness of a patient self-management program for basic foot care among older adults over a 6-month period. (109) Seventy-eight participants were randomized to receive the self-management treatment and 75 to the usual care, which was self-referral to a podiatry department. At the end of the study, participants in the intervention group had lower foot disability scores compare to the usual care group. A 1-unit score difference was observed between the two arms, (95% C.I. -2, 0). No cost difference was observed between the two treatment regimens indicating that self-management had better outcomes for a similar cost.

Similarly, Miaskowski and colleagues examined the effectiveness of a self-care intervention to improve cancer pain management in a randomized controlled clinical trial. Patients receiving a psycho-educational intervention (n=93) were compared to those under standard care (n=81) (patient version of the Cancer Pain Guideline published by the Agency for Health Care Policy and Research (AHCPR)). Those in the intervention arm were taught how to use a pillbox and were given information on how to communicate with their doctor about their pain and eventual

changes in their prescriptions. In addition, two follow-up home visits and three phone calls were offered by a coaching nurse to both arms. The result of the study showed a reduction in pain intensity scores in the intervention arm compared to the standard care arm (110).

Concerning HIV, several self-management interventions have been conducted, as people with deadly must take their medication as prescribed for many years. (111) For example, a recent quasi-experimental study compared the effectiveness of a virtual self-management intervention versus traditional follow-up among people living with HIV over a period of 3 to 4 months. The intervention (n=99) consisted of four virtual nurse intervention (interactive) sessions, each 20-30 minutes long. The control or traditional follow-up (n=80) was based on a face-to-face meeting with health care professionals.

The comparison was made with regard to self-reported adherence to antiretroviral treatment (ART). Selected participants were on ART treatment for 11 years (111). Medication adherence was the primary outcome. The authors also looked at self-efficacy, attitude toward medication intake, symptom-related discomfort, stress, and social support. Adherence at baseline was high, 80 and 84 % respectively for the traditional and virtual follow-up groups. The results of the study indicated a significant adherence improvement in both groups but non differential by group at six months, 93% for the traditional group and 90% for the virtual group.

Similarly, Millard and colleagues conducted a systematic review on self-management education programs among people living with HIV/AIDS (112).This

review indicated that self-care programs resulted in short term improvements in physical, psychosocial, health knowledge and behavioral outcomes in this population. In most studies included in the review, the improvements were highly significant in the intervention group compared to the control (112).

To conclude, there is evidence that self-care interventions can result in improvements in chronic disease care. However, more rigorous studies are needed that consistently use randomized controlled trial designs, blinded data collection, and that examine longer-term outcomes.

2.3 Self-management and depression

Self-management interventions including qualitative studies and randomized controlled trial studies have also been evaluated for depression. For example, Grieken et al explored depression recovery strategies among patients. Focus group discussions were organised to collect patients' opinions. The findings indicated that being engaged in activities, contact with fellow sufferers, proactive attitude towards the disease and treatment were, among others, strategies which could help patients recovering from the disease (112).

Several clinical trials have been done. For example, McCusker et al (113) examined a telephone-supported depression self-care intervention in 223 self-referred adult patients with chronic physical illnesses but not eye disease. Patients were assigned to either the intervention group (toolkit including Antidepressant Skills Workbook in paper and audio versions, a mood monitoring tool and an informational DVD plus telephone coaching) or to the control group (toolkit without coaching). PHQ-

9 scores declined significantly in both groups over the 6-month follow-up. The PHQ-9 scores were significantly lower at 3 months in the intervention group but not at 6 months indicating that coaching was helpful at first but that the effect then diminished over time. The effect sizes at 3 and 6 months were 0.44, 95% CI =0.16-0.72 and 0.24, 95% CI = -0.01-0.60 respectively. There was no significant effect of the toolkit on the secondary outcomes of self-efficacy, satisfaction and the use of health services at six months.

A recent study looked at the use of a self-care intervention to improve confidence in patients with depression and chronic illnesses (114). Two hundred and fourteen patients with comorbid depression and poorly controlled diabetes and/or coronary heart disease were included in a 12-month study. The outcome measured were improvements in knowledge and self-care efficacy. The intervention package included: a depression help book, a depression care DVD, a chronic disease management booklet and other materials and self-monitoring devices. Visits were scheduled bimonthly or every three weeks with intervention nurses of the regular physician in order to create clinical and self-management goals. The aim of these visits was to monitor patient progress on depressive symptoms (PHQ-9), medical disease control and self-care activities. The results of the study indicated a highly significant improvement in confidence for self-care, namely with regards to the ability to follow through with medical regimens.

Another study focused on the prevention of depression and anxiety in older adults living in 14 residential homes in Amsterdam. One hundred and twenty-nine

participants with scores of 8 or higher on the Centre for Epidemiologic Studies Depression Scale (CES-D) were randomized either to the intervention group or to usual care. The intervention consisted of a self-help module on activity scheduling, a program in which patients were given information on how to monitor their mood and design a daily activity plan while the usual care included any form of appropriate health care. The authors examined the improvement in the level of depressive and anxiety symptoms (115). No significant difference was observed between the two arms. Only 21% of the participants completed the intervention, with a mean age of 84 years. They concluded that guided self-help interventions might be difficult to apply in very old and vulnerable individuals living in residential homes.

Also, Johansson and colleagues conducted a 10-week internet-based psychodynamic guided self-help intervention for adult depression (116). The objective of the study was to improve access to psychological treatment for depression among this population. The Mini-international Neuropsychiatric interview was used to diagnose depressive symptoms. Participants were randomized to either the treatment or control group. The intervention included nine treatment modules based on psychodynamic principles with online therapist contact. On the other hand, the active control was based on a structured support intervention coupled with psycho-education and weekly online contact. The result of the study indicated a highly significant improvement in depressive symptoms in the intervention group compare to the control. The Cohen's d effect size was estimated at 1.11.

Gellatly and Coventry carried out a systematic review of cognitive behavioral therapy (CBT) among chronic obstructive pulmonary disease (COPD) patients with mild-to-moderate anxiety and depression. Only studies targeting controlled trials evaluating the effectiveness of CBT for treating mild-to-moderate anxiety or depression in adults with clinically stable COPD were included. The review did not find evidence that CBT coupled with exercise training and education could significantly reduce anxiety and depressive symptoms among patients with chronic obstructive pulmonary disease.(117)

Finally, Gellatly conducted a systematic review in 2007 on factors that affect the effectiveness of self-care interventions in depression treatment. Randomized controlled trials on the effectiveness of self-help interventions in the treatment of depressive symptoms were identified. Thirty-four studies were selected. In unadjusted analyses, factors like unclear allocation concealment, observer-rated outcome measures and waiting-list control groups, non-clinical setting recruitment, the inclusion of patients with existing depression, contact with a therapist (guided self-help) and the use of cognitive behavioural therapy techniques were associated with greater effectiveness. However, in adjusted analyses, only guided self-help was associated with greater effectiveness compared to pure self-help, (p= 0·03).

2.4 Self-management, depression and eye diseases

As mentioned in Chapter 1, Section IV, research has indicated an association between age-related eye disease and depression, especially in those with (AMD) and DR (81, 82, 87). However, no studies have examined the use of self-management

interventions on depressive symptoms in this population. A few studies have, though, found that brief psychological interventions (greater than 3 hours of professional support) can be effective.

In a randomized controlled trial, Brody et al examined the 6-month efficacy of a brief psychological intervention in reducing depressive symptoms. The sample included 32 clinically depressed patients with AMD with a mean age of 81.5 years (118). The recruitment was done at the University of California ophthalmology clinics. The 15-item Geriatric Depression Scale (GDS-15) questionnaire was used to assess depression severity. Patients were included in the study if they had minor or major depressive disorder with significant depressive symptoms (≥ to 5 points on the GDS-15). Participants in the intervention group were given a 12-hour brief psychological intervention program comprised of health education and enhancement of problem solving skills. The results of the study indicated a statistically significant reduction in depressive symptoms in the intervention arm compared to the control arm or waiting list, P=.03 (118).

In a larger study, Brody also examined the 6-month efficacy of the same 12-hour brief psychological intervention on outcomes like depressive symptoms, self-efficacy, and self-reported visual function in 214 patients with AMD. The intervention included cognitive and behavioral components, especially information about AMD, problem solving skills and a simple exercise program. Participants in the intervention group were compared to those on the waiting list. They were all followed-up for a six month period (119). Emotional distress was the main outcome. The authors also

looked at depression status, visual function and self-efficacy. The findings showed less distress in the intervention group compared to the control group, p=. 0008. Also, better function and increased self-efficacy were observed, with a p-value of .05 and 0.006 respectively. In addition, the incidence of clinical depression was significantly lower in the intervention group compared to the control group, p=0.05.

Another study examined the role of problem solving treatment (PST) in preventing depression symptoms in people with AMD. Using a randomized controlled trial design, patients exposed to problem solving treatment were compared to those under usual care. The main outcome measure was the reduction of depression incidence and the secondary outcome was the loss of valued activities. Those in the intervention arm received six 45 to 60 minute PST sessions at their domicile in an 8-week period versus usual care in the control arm. The intervention included knowledge on problem solving skills such as problem definition, establishing realistic goals, identifying solutions and evaluating outcomes. The result of the study indicated a reduction in the incidence of depression in the intervention group at 2 months compared to the control (OR = 0.43; 95% CI [0.20, 0.95]. However, this reduction was attenuated at 6 months and was no longer statistically significant (OR = 0.53, 95% CI [0.28, 1.01].(120)

Another recent study assessed mood, memory, and diabetes mellitus self-management skills among older African Americans with DR in the US. The diabetes mellitus self-management scores was significantly lower among participants with depression and memory impairment compared to those without depression or with

normal memory, p<.001 and p<0.002 respectively. No self-care interventions have previously been tested in patients with diabetic retinopathy to our knowledge.

2.5 Introduction to the project

This is the first preliminary study that focuses on the use of self-care or self-management tools in reducing depressive problems in older people with age-related eye disease. Various tools were used to collect data necessary to explore this topic. These include:

- The Patient Health Questionnaire (PHQ-9), a 5-minute valid and reliable 9 item instrument, was used to measure depressive symptoms. The scores range from 0 to 27, with cut points of 5, 10, 15 and 20 representing mild, moderate, moderately severe, and severe levels of depression, respectively. The PHQ-9 has 92% sensitivity and 73% specificity.

- The Generalized Anxiety Disorder 7 item questionnaire (GAD-7) with good sensitivity and specificity was used to evaluate anxiety symptoms. Scores of 5, 10, and 15 are taken as the cut-off points for mild, moderate and severe anxiety, respectively

- The Blessed Orientation-Memory-Concentration test was used to measure cognitive impairment. Scores range from 0 to 28, with a score of 10 of greater indicating signs of dementia.

- The Life Space Assessment questionnaire was used to assess patient mobility. Scores range from 0 to 120 with higher scores representing greater mobility.

- Self-efficacy was measured using an adapted version of a validated diabetes self-care self-efficacy scale

- Presenting visual acuity in the better eye was taken from the medical record as measured by a Snellen chart.

All potentially eligible patients were screened at the Maisonneuve Rosemont ophthalmology clinic using these tools. Additional details concerning the data collection process namely the study design, the study population, the intervention, the recruitment, the sample size and the statistical methods used as well as the results of this study are presented in the next chapter.

Chapter 3: Methods and Results

Self-care tools to treat depressive symptoms in patients with age-related eye disease: A randomized controlled clinical trial

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3.1 Abstract

Purpose: Depression is a common problem in people with age-related macular degeneration (AMD) and diabetic retinopathy (DR). Antidepressants and psychotherapy are often underutilized. Our goal was to determine if self-care tools plus limited telephone support could reduce depressive symptoms.

Methods: A single-blind randomized controlled clinical trial was conducted at Maisonneuve-Rosemont Hospital in Montreal, Canada. All eligible patients were invited to participate in the trial. To be eligible, participants must have had either late stage AMD or DR, at least mild depressive symptoms, and visual acuity better than 20/200. Half were randomized to the intervention arm and half to delayed intervention/usual care. The intervention consisted of large print written and audio tools incorporating cognitive-behavioral principles plus three 10-minute telephone calls from a coach. Eight-week follow-up data were collected by telephone. The primary outcome was the 8-week change in depressive symptoms as measured by the Patient Health Questionnaire (PHQ-9).

Results: Eighty participants were recruited while 10 were lost to follow-up (12.5%) giving 70 with complete data. The mean baseline PHQ-9 score was 9.5 (SD=3.9) indicating moderate depressive symptoms. The average decrease in PHQ-9 scores over the 8 weeks was 4.9 (SD=4.2) in the intervention group and 3.2 (SD=4.6) in the usual care group, a 1.7-point difference (p=0.104). After adjusting for baseline imbalances in visual acuity, antidepressant use, and participation in psychotherapy, the difference increased from 1.7 to 2.3 and became statistically

significant (P=0.037). Sixty percent of those in the intervention group reported having used the tools at the end of the study.

Conclusions: Self-care tools plus telephone coaching led to a small improvement in depressive symptoms in patients with age-related eye disease. Additional research into the best way to support depressed patients with age-related eye disease is necessary.

3.2 Introduction

Depression is a common problem in people with age-related eye disease as 29-39% of adults with age-related macular degeneration, Fuchs' corneal dystrophy, or glaucoma experience depressive symptoms (81). Although antidepressants and psychotherapy are effective treatments, they remain underutilized as 35% of depressed primary care patients have never received any depression treatment (121). Among those who have tried treatment, antidepressants can cause unpleasant side effects leading to high rates of discontinuation (97). Research shows that older adults with depression prefer psychotherapy by a 2:1 ratio over antidepressants (98). Yet, psychotherapy in the private healthcare system is expensive, wait times in the public system can be long (122), and there is still a stigma towards psychotherapy in some populations (123). Therefore, the investigation of alternative treatments for depression is important.

There is already evidence that brief psychological interventions can decrease depressive symptoms or reduce the incidence of depressive symptoms in patients with AMD, at least in the short-term (119, 120, 124). Brief psychological interventions typically take between 6 and 10 hours of time and are delivered by a health professional either in a group format or one-on-one in the home. These interventions are very promising, yet the time needed to deliver the intervention increases its cost and decreases its feasibility to be widely offered as a routine part of vision care.

Therefore, we decided to investigate whether depression self-care tools, which are defined as requiring less than 3 hours of professional support (125),

could decrease depressive symptoms in patients with age-related eye disease. Self-care (sometimes referred to as self-management) interventions are advocated as an essential part of chronic disease care (106). These interventions typically include components on behavioral activation and problem solving (106). Meta-analyses indicate that depression self-care interventions can be useful although most studies have been carried out in younger, non-clinical, self-referred populations (125). No studies to our knowledge have examined self-care interventions and their effect on depressive symptoms in patients with age-related eye disease.

Our hypothesis was that self-care tools plus limited telephone coach support would decrease depressive symptoms and anxiety while increasing life space and self-efficacy in a population with age-related eye disease. We chose to conduct this trial in patients with (AMD) or (DR) since the prevalence of depression in these groups is high (81, 126) and since both groups experience losses in visual acuity.

3.3 Methods

3.3.1 Study Population

Participants were recruited from the retinal clinics of Maisonneuve-Rosemont Hospital in Montreal, Canada from November 2014 through December 2015. Eligibility criteria included age >50, a clinical diagnosis of late stage age-related macular degeneration or any stage of diabetic retinopathy, a score of 5 or greater on the Patient Health Questionnaire 9-item depression scale indicating at least mild depressive symptoms(127), visual acuity in the better eye better than 20/200, a score of less than 10 on the Blessed-Orientation-Memory-Concentration

(BOMC) test indicating adequate cognition to participate in the study (128), and a signed informed consent form. An exclusion criterion was if the person was already in cognitive behavioral therapy (CBT). All participants were paid $40. The ethics board of Maisonneuve-Rosemont Hospital approved the study and the tenets of the Declaration of Helsinki were observed.

3.3.2 Recruitment

All potentially eligible patients were approached in the waiting room and informed about the study (see flow chart, list of figures). Those interested were then asked to sign the consent form and were assessed for eligibility.

3.3.3 Study Design

An 8-week single-blind randomized controlled clinical trial was conducted. Participants were randomized to the intervention arm or the usual care arm. The randomization sequence was obtained using a random number generator website with a block size of four. Assignments were individually inserted into ordered sealed envelopes that were opened in front of the participant. Those in the intervention group received the self-care tool intervention plus up to three coaching phone calls. Both groups were called 8 weeks after recruitment by telephone by an interviewer masked to treatment assignment and were given a follow-up questionnaire. After the follow-up questionnaire was completed, the usual care group received the self-care tools by mail plus one coach call. The CONSORT guidelines for non-pharmacologic interventions were followed (129). The trial was registered at clinicaltrials.gov.

3.3.4 Intervention

The tools were used previously in a clinical trial among middle-aged and older primary care patients with chronic physical conditions but without vision loss (113). To determine if the tools needed modification for patients with vision loss, they were evaluated in July 2014 in a pilot study of 10 people with low vision and a history of depression. The general consensus from this pilot study was that the tools were useful but that the print should be further enlarged from 14-point to 18-point font and the contrast should be further enhanced. These modifications were made prior to study inception.

The toolkit consisted of a 3-ring binder notebook filled with written tools using 18-point font as well as audio tools. Two of the tools incorporated cognitive-behavioral therapy principles: the Antidepressant Skills Workbook (written and audio versions) (130) and a Mood Monitoring tool. These two tools along with a DVD on depression were the three core tools of the toolkit. The other tools were only recommended to those the coach thought would benefit: a relaxation CD, information on low vision resources, information on medication misuse and emotional eating, and information for family members on how to be supportive. In addition, participants were offered support in the form of three 10-minute phone calls from a trained coach to encourage use of the tools and answer questions. These calls were recorded to ensure the fidelity of the intervention. Less frequent phone calls were also an option, if preferred. The coach, who was a former nurse,

underwent 15 hours of training by an experienced psychotherapist with experience in self-care tools. The usual care group received the toolkit after the follow-up interview and at that time received one coach call.

3.3.5 Data Collection

Data were collected at both baseline and the 8-week follow-up. The interviewers were masked to the treatment assignment of the participant. Depressive symptoms were measured with the PHQ-9 instrument (92% sensitivity, 73% specificity)(127). This 9-item instrument is a valid and reliable measure of depressive symptoms, with cut points of 5, 10, 15 and 20 representing mild, moderate, moderately severe, and severe levels of severity, respectively. The GAD-7 was used to evaluate anxiety symptoms (131). This 7 item questionnaire has demonstrated very good sensitivity (89%) and good specificity (82%) (131).

Life space, which measures the spatial extent of a person over the last month, was measured using the Life Space Assessment (LSA) (132). This was particularly measured as depressive people tend to isolate themselves from others. As mentioned in the literature section, Limited mobility or a low spatial extent could be associated with depression. The LSA measures the frequency of going to 5 life space levels (places inside house but outside bedroom, places just outside home, places in neighborhood, places outside neighborhood but within city, places outside city) and whether technical or personal assistance was required. Scores range from 0 to 120 with higher scores representing greater life space. This tool has been found to be valid and reliable (132). Self-efficacy with regard to depression self-care was measured using an adapted version of a validated diabetes self-care self-efficacy scale (133). Four statements were read

(e.g. I am able to carry out daily activities that keep my mood positive). Participants had to rate their level of agreement with responses ranging from strongly disagree to strongly agree on a 4 point scale. Cognitive Impairment was measured with the Blessed Orientation-Memory-Concentration test (BOMC)(128).

Patients with a score of 10 or greater, having signs of dementia or cognitive impairment were excluded from the study while those with normal cognition (scores 0-5) and those with mild cognitive impairment (scores of 5-9) were included. Participants were asked about physician diagnoses of 13 chronic medical conditions (e.g. arthritis, diabetes, and stroke) including depression and about prescription medications taken for low mood or anxiety. Demographic information on age, gender, race, and education were collected. Presenting visual acuity in the better eye was taken from the medical record as measured by a Snellen chart. Scores were then converted to the log of the minimum angle of resolution (logMAR). Any adverse events that happened during the study period were recorded. At the end of the follow-up interview, masking was broken and participants were asked about the tools that they used during the follow-up period.

Additional information was recorded by the coach. The coach recorded information about the date of the call, the needs of the participant, and the tools that were used and recommended for next time.

Efforts were made to maximize follow-up and minimize missing data. The coach was instructed to encourage participants to allow the follow-up interviewer to contact them even if participants did not want to engage in coaching or use the toolkit.

3.3.6 Primary and Secondary Outcomes

The primary outcome was the 8-week change in PHQ-9 depressive symptoms. Secondary outcomes included 8-week changes in life space, anxiety, and self-efficacy.

3.3.7 Statistical Analysis and Power

Baseline characteristics were compared between the intervention and usual care groups to ensure that the randomization process worked. Clinically significant imbalances were noted. The difference between the baseline and the follow-up value was calculated for each outcome with positive values indicating an improvement and negative values indicating a worsening. Student's t-tests were used to determine whether the intervention group had greater changes in the outcomes than the usual care group. Linear regression was used to adjust for any baseline variables that had clinically important imbalances between the intervention and usual care groups.

Interaction was assessed to examine whether the intervention only worked in certain subgroups, e.g. AMD versus DR status, those with greater education, milder depressive symptoms, better vision, better cognition, or more self-efficacy. Interaction terms were tested for statistical significance in linear regression models. Statistically significant interactions were further examined in stratified analyses. For the primary outcome, intention-to-treat analyses using multiple imputations to replace missing outcome data for those lost to follow-up and

complete case analyses were done. For the secondary outcomes, only complete case analysis was done. Analyses were done using Stata Version 11 (College Station, Texas).

With at least 35 people in each group and an average standard deviation of the change in PHQ-9 scores of 4.4, we had 80% power to detect a 3-point difference in the 8-week change scores between the intervention and usual care groups. An individual change of 5 or more on the PHQ-9 is considered clearly clinically significant (134, 135) while a change from 2.5-4 is considered to be borderline clinically significant (134, 135).

3.4 Results

The recruitment and retention rates are described in Figure 1. We reviewed 2,986 charts to determine phase 1 eligibility (diagnosis, age, and visual acuity). Of those with phase 1 eligibility (n=1,223), 258 people (21%) agreed to be evaluated for phase 2 eligibility (i.e. PHQ-9, BOMC) with 80 people meeting all eligibility criteria. Eighty people were randomized in block sizes of 4, which led to 39 in the usual care group and 41 in the intervention group. We lost 10 people to follow-up, 6 in the intervention group and 4 in the usual care group giving 35 in each group. Those lost to follow-up were fairly similar to those who completed the study in terms of age, visual acuity, education, and baseline depression and anxiety scores (P>0.10) (data not shown).

The mean age of the sample was 76 years old (SD=12) while 38% were men. Fifty-five percent of the sample had AMD while 45% had DR. The mean logMAR visual acuity in the better eye was 0.37 (SD=0.2) (20/50 Snellen acuity) and the mean PHQ-9 score was 9.5 (SD=3.9). Despite everyone in our sample

having at least mild depressive symptoms, very few people were receiving treatment for depression. Overall, 4% were involved in non-CBT psychotherapy while 20% were taking antidepressants. The baseline characteristics of the two treatment groups were fairly similar (Table 1). There were some imbalances, though, in visual acuity, use of antidepressants, and use of psychotherapy. These variables were chosen to include in regression models given their imbalance and their potential importance to depression levels.

Both the intervention group and the usual care group had a decrease in depressive symptoms over the 8-week follow-up period although the decrease in the intervention group was slightly greater (mean 4.9, SD=4.2) than the usual care group (mean 3.2, SD=4.6) (Table 2) giving an overall difference of 1.7 points between the two groups. This difference was not statistically significant (p=0.104). However, when we adjusted for visual acuity, antidepressant use, and psychotherapy use, the difference increased to 2.3 and became statistically significant (p=0.037). Analyses using multiple imputation to replace missing outcome values for the 10 people who were lost-to-follow-up gave similar results (P=0.134 for the unadjusted results and P=0.030 for the adjusted results). The intervention had minimal effects on the secondary outcomes (p>0.10 for both unadjusted and adjusted results) (Table 2). No statistically significant interactions were detected with level of depressive symptoms, cognitive impairment, educational level, visual acuity, self-efficacy, or eye disease diagnosis.

The intervention did not motivate people to initiate standard therapy for depression over the 8-week follow-up period. Three people (4%) reported currently receiving non-CBT therapy or counseling at follow-up, two of whom started it

during follow-up. One was in the intervention group and one was in the usual care group. Fourteen people (20%) reported currently taking medications for emotional or mood problems at follow-up. Three of the 14 initiated these medications after the start of our study, one in the intervention group and two in the control group.

To better understand why our intervention did not have a greater effect, we examined the frequency of tool use reported to the coach by the number of coach contacts (Table 3). Of the 33 people who had at least 1 coach call, 21% had one coach call, 27% had two, and 52% had three. Overall, 70% reported using any of the three core tools to the coach. This differed by the number of coach calls as only 29% reported using the core tools if they had only one coach call whereas over 78% reported using any core tools if they had two or three coach calls. The report of tool use was a bit lower when reported to the follow-up interviewer at the end of the study as at that time only 60% reported using any tools.

Reasons given to either the coach or the follow-up interviewer for not using the tools including having difficulty with vision (40%), being too busy (50%), not interested (20%), not identifying with a label of depression (10%), and technical problems with the audio tools (20%). Those in the intervention group who reported using a tool did not have a significantly different change in depressive symptoms compared to those in the intervention group who did not use a tool or those in the usual care group (p=0.265). No variables were statistically significantly associated with tool use among those in the intervention group although those who used the tools had three more years of education on average than those who did not use the tools (12 years versus 9 years, p=0.064) and

women were much more likely to report using the tools than men (70% versus 33%, p=0.071). Further studies should focus on the low use of these tools.

3.5 Discussion

The aim of this study was to evaluate whether self-care tools plus minimal telephone coaching (<3 hours professional support), could alleviate depressive symptoms in patient with age-related eye disease. This is the first study addressing the high rates of depressive symptoms in this population. Our intervention had a small effect by reducing depressive symptoms more than usual care by 2.3 points, on average. The minimum clinically important difference on the PHQ-9 is 5, although changes of 2.5-4 are considered to have borderline clinical significance (134, 135). There was no effect of the intervention on our secondary outcomes of anxiety, life space, or self-efficacy.

Depressive symptoms decreased over the 8-week period in both groups: by 3.2 points in the usual care group and 4.9 points in the intervention group. The decrease in the usual care group may be due to the natural history of depression or to regression to the mean, a statistical phenomenon that occurs when multiple measurements are taken on a single person and a threshold is used to determine eligibility for the study (136). Participants were only eligible if they had a score of at least 5 on the PHQ-9 so on average; we expected scores to decrease over time. The use of a randomized comparison group allowed us to determine if our intervention had an effect beyond this expected decrease.

To understand why the intervention did not have a greater effect, we examined the frequency of tool use as reported to the coach and the follow-up interviewer. Tool use as reported to the coach was slightly higher (70%) than that

reported to the follow-up interviewer at the end of the study (60%). This could either be because participants had forgotten that they had used the tools earlier in the study or that some had falsely reported using the tools to the coach in an attempt to give a socially desirable answer. The reasons for not using the tools (e.g. too busy, difficulty with vision) may indicate that the tools were not sufficiently user-friendly for this population despite our attempts to enlarge the font and to provide audio versions of the tools. Certainly, to be effective, self-care tools require self-motivation, a willingness to be introspective, and a commitment to do the recommended exercises, and those may have been unreasonable expectations for much of this population as only 49% of those in the intervention group completed all three coach calls and 10 people (12.5%) were lost to follow-up over the 8 weeks.

We know from the literature that self-care tools can be effective for depression but many of the studies with positive results were done in self-referred, younger populations rather than older, clinical populations approached in a systematic way (125). Given our modest results, it may be that greater coaching support is required or that a more intensive intervention, such as the brief psychological interventions found effective previously, are better approaches in older adults with vision loss. Rovner *et al* conducted problem-solving therapy in patients' homes (120) while Brody *et al* conducted group self-management sessions at a university (119). Both approaches led to clinically significant reductions in depressive symptoms or in the incidence of depression. The disadvantages of these approaches are that they cost more to implement on a

large scale and they require either an ability to travel frequently to the hospital for group sessions or a willingness to invite a person into the home.

Strengths of this study included the randomized controlled clinical trial design, the blinded nature of the data collection, and the novel examination of self-care tools in a population of people with age-related eye disease. We had more than enough statistical power to detect an effect that was clinically significant (PHQ-9 change of >=5) or borderline clinically significant (PHQ-9 change of 2.5-4). A limitation is that 12.5% were lost-to-follow-up. However, our results were unchanged when we used multiple imputations to replace missing values. In addition, the 8-week follow-up may have been too short to see an effect and perhaps this population of older adults with visual impairment and about 1/5 with mild cognitive impairment would have benefited from more than three coaching calls.

In conclusion, our intervention had a small benefit on depressive symptoms in patients with age-related eye disease. Additional research into the best way to support depressed patients with age-related eye disease is necessary for patients to optimally participate in their vision treatment regimen.

4 Figure1: Recruitment and retention flow chart

Screening

Phase 1 eligibility (n=1,223)

☐ Declined to participate (n=965)

Enrollment

Assessed for Phase 2

Excluded (n=178)

☐ Not meeting inclusion

Randomized (n=80)

Allocation

Allocated to receive self-care tools plus

Allocated to receive usual care

Follow-Up

Lost to follow-up (n=6)

Withdrawal (n=4)

Lost to follow-up (n=4)

Withdrawal (n=4)

Analysis

Analyzed (n=35)

Analyzed (n=35)
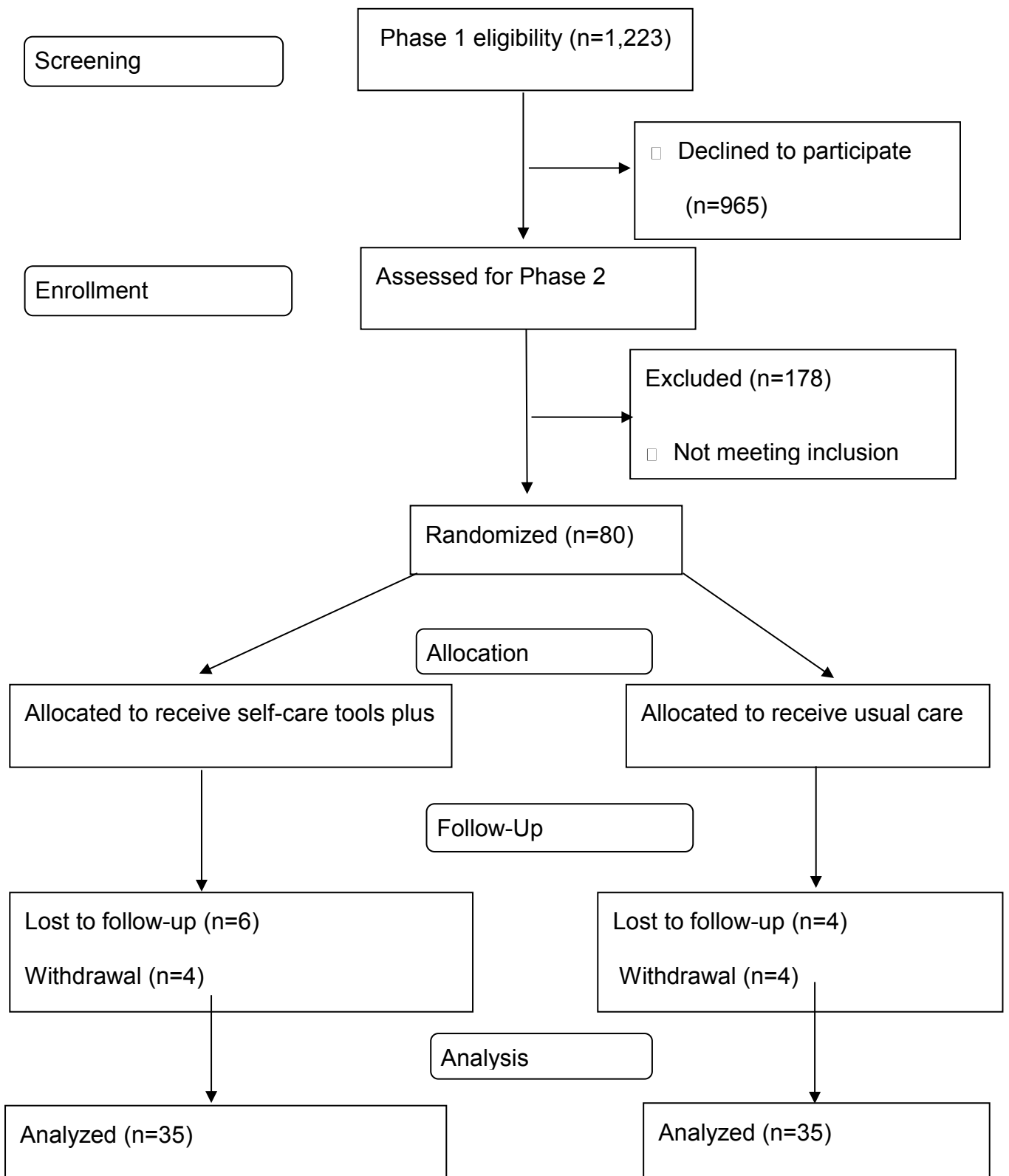
5 Table 1: Baseline characteristics of participants by treatment assignment

	Self-Care Intervention n=41 Mean (SD) or %*	Usual Care n=39 Mean (SD) or %*
Age, Years	75.1 (11.1)	73.0 (10.8)
Gender		
Male	34%	41%
Female	66%	59%
Education, Years	10.9 (4.1)	11.3 (3.8)
Median Visual Acuity (IQR), logMAR	0.36 (0.18)	0.30 (0.24)
Diagnosis		
AMD	54%	56%
DR	46%	44%
No. of Co-morbidities	4.0 (2.2)	3.6 (2.1)
Mild Cognitive Impairment	17%	23%
Using Antidepressants	9%	23%
Undergoing Psychotherapy (but not CBT)	7%	0%
PHQ-9 Depression	9.5 (3.7)	9.5 (4.2)
GAD7 Anxiety	6.0 (5.1)	5.8 (5.1)
Life Space	47.2 (26.9)	44.6 (24.0)
Self-Efficacy	7.7 (1.8)	8.1 (2.0)

*Unless otherwise specified

Abbreviations: IQR=interquartile range; logMAR=log minimum angle of resolution; CBT=cognitive behavioral therapy; AMD=age-related macular degeneration; DR=diabetic retinopathy

*Visual acuity, use of antidepressant and psychotherapy were not balanced between the groups

6 Table 2: Eight-week change values* by treatment assignment

Outcome	Intervention			Usual Care			P-value†	P-value‡
	Baseline Mean (SD)	Follow-up Mean (SD)	Change* Mean (SD)	Baseline Mean (SD)	Follow-up Mean (SD)	Change* Mean (SD)		
Depressive Symptoms	9.1 (3.5)	4.2 (4.0)	4.9 (4.2)	9.2 (4.2)	6.0 (4.3)	3.2 (4.6)	0.104	0.037
Anxiety Symptoms	6.4 (5.3)	3.2 (3.5)	3.2 (5.6)	5.5 (5.1)	3.8 (3.9)	1.7 (5.0)	0.245	0.205
Life Space	46.3 (28.1)	44.1 (22.2)	-2.2 (24.3)	45.0 (23.7)	41.7 (19.9)	-3.9 (19.6)	0.751	0.653
Self-Efficacy	7.7 (1.7)	8.3 (1.7)	0.5 (2.2)	7.9 (2.1)	8.1 (1.3)	0.2 (2.2)	0.532	0.568

*Positive change scores indicate improvements over the 8 week period. Negative change scores indicate a worsening.
† Student's t test comparing the change in the intervention group to the change in the usual care group.
‡ Linear regression model adjusting for visual acuity, use of antidepressants, and use of psychotherapy

7 Table 3: Use of tools by those in the intervention group according to coach log (n=33*)

Tool Used	1 coach contact n=7	2 coach contacts n=9	3 coach contacts n=17
Antidepressant Skills Workbook	29%	78%	71%
DVD on Depression	0%	33%	24%
Relaxation CD	0%	44%	24%
At Least One Core Tool Used	29%	78%	82%
Additional Resources	0%	11%	6%
Medication Misuse	0%	0%	0%
Emotional Eating	0%	22%	12%
Family Support Booklet	0%	0%	0%

*Two people did not receive any coach calls

Chapter 4: Discussion

4.1 Self-care intervention for depression in old population with aged related eye diseases

This is the first study to assess the use of self-care tools to reduce depressive symptoms among older adults with limited vision. We hypothesised that the tools could reduce depressive and anxiety symptoms or possibly increase self-efficacy and life space in older adults with age-related macular degeneration or diabetic retinopathy. A randomized controlled trial was conducted to assess this hypothesis. The results of the study showed that self-care tools, with limited phone support could alleviate depressive symptoms among these populations although the effect was small.

It is however important to point out the percentage of participants who reported using the tools was lower than expected, only 60%. Among the reasons cited for not-using the intervention material, a lack of motivation, visual difficulties with the material, a resistance to being labeled "depressed", and technical difficulties were often cited. Although evidence of the efficacy of self-care tools on depression has largely been documented in younger, non-clinical and self-referred populations, our study participants were relatively older with limited vision. Moreover, the study sample was not self-selected as seen in previous studies: all willing individuals were invited to participate. This may be why the effect of our intervention was smaller than that found in previous studies. Furthermore, there were no effects of the intervention on anxiety,

life space, or self-efficacy. Although we hypothesized that the Antidepressant Skills Workbook would have an effect on all the outcomes, perhaps a longer follow-up period was necessary to see an impact of the tools on these secondary outcomes or perhaps the intervention did not target these secondary outcomes sufficiently. Additional studies are needed to further understand the potential of self-care tools to reduce depressive symptoms and improve the quality of life among older populations with age-related eye diseases. It's necessary to identify new strategies in order to make the tools more appealing and user friendly to this population. Additional focus groups should be held among those with vision loss so as to determine the best way to develop and carry out this intervention among this population.

4.2 Strength and limits of the study

We conducted an 8 week study to evaluate the intervention. The duration of the study may have been too short for this population to see a larger, more clinically significant effect. However, we thought that any effect would be strongest in the first few months and would then taper off after the novelty of the tools wore off. Furthermore, the funding available was not sufficient to cover a longer study period.

Also, the single blind nature of the intervention might have introduced some bias in the results. The participants knew which group they were assigned to, either the intervention or the control group. Thus, they might have reported information differently at follow-up depending on their assigned group. For example, those who received the intervention might have reported fewer depressive symptoms because they felt it was more socially desirable to indicate that the intervention had been

44

helpful. A double-blinded study would have been more rigorous. However, we struggled to imagine an intervention for the control group that would not have any effect on depressive symptoms and that we could develop in the short time frame we had available to do this study. Future research should consider developing a placebo that will not affect depressive symptoms in order to carry out a double blind study in this setting.

In the sample size calculation, we assumed that about 15% of our participants would be lost to follow up, given the age of the population and their vulnerability. At the end of the follow up, 12.5% decided to drop out of the study or were simply not reachable. Missing data are always a concern for bias. However, the descriptive statistics showed similarities in the characteristics of those who remained in the study compared to those lost to follow up. Also, we performed multiple imputation, the gold standard way of dealing with missing data, to deal with the losses to follow up. The results of the study did not change when taking the losses to follow up into account.

With regards to the strengths of the study, this is the first study to examine the use of self-care tools to alleviate or reduce depressive symptoms among older adults with age- related eye disease. To our knowledge, no study has been done in this regard, especially in patients with AMD or DR, who are most at risk for depressive symptoms. In addition, we used a randomized controlled trial design, which is the gold standard study design for evaluating efficacy. Moreover, all eligible participants were approached about participation in the study instead of just relying on self-referred

patients as many other self-care studies have done. This increases the generalizability of our results.

4.3 Clinical implications and future research

This study was the first step in examining the short-term efficacy of self-care tools in reducing depressive symptoms in this population. The results indicated that these tools could be useful but that the effect needs to be maximized in order to be more clinically significant. Further research including a longer follow up period and strategies to maximize the effect such as more coaching calls or alternative ways of delivering the intervention are needed. If the efficacy of self-care tools to treat depressive symptoms is confirmed, this could be a significant step in the treatment of depression among older adults with age-related eye diseases. Identifying alternative treatment options that are accessible and less costly could be a big advancement in the treatment of depression. The identification of such a treatment might not only contribute to the reduction of the burden of the disease as a whole but increase adherence to the visual treatment regimen, reduce vision loss, and improve patient quality of life. Such tools could be integrated into the low vision rehabilitation program or be offered in ophthalmology and optometry clinics.

ReferencesUncategorized References

1.	Canada PHAo. What is depression 2014 [2014-12-22]. Available from: http://www.phac-aspc.gc.ca/cd-mc/mi-mm/depression-eng.php.
2.	WHO. Depression 2012 [2015-09-15]. Available from: http://www.who.int/topics/depression/en/.
3.	WHO. Depression 2015 [2015-09-27]. Available from: http://www.emro.who.int/health-topics/depression/index.html.
4.	Canada S. Mood disorders by age group and sex (number) 2014 [2015-06-17]. Available from: http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/health113a-eng.htm.
5.	PHAC. A report on mental illness in Canada 2012. Available from: http://www.phac-aspc.gc.ca/publicat/miic-mmac/chap_1-eng.php.
6.	Canada H. Mental Health- Depression 2009 [2009-02-09]. Available from: http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/diseases-maladies/depression-eng.php.
7.	Dewa CS, Goering P, Lin E, Paterson M. Depression-related short-term disability in an employed population. J Occup Environ Med. 2002;44(7):628-33.
8.	Lim KL, Jacobs P, Ohinmaa A, Schopflocher D, Dewa CS. A new population-based measure of the economic burden of mental illness in Canada. Chronic Dis Can. 2008;28(3):92-8.
9.	CAMH. Mental Illness and Addictions: Facts and Statistics 2012 [2015/09/17]. Available from: http://www.camh.ca/en/hospital/about_camh/newsroom/for_reporters/Pages/addictionmentalhealthstatistics.aspx.
10.	Healthline. Risk factors for depression 2014 [2015-09-18]. Available from: http://www.healthline.com/health/depression/risk-factors - Overview1.
11.	Bechtel W. Circadian Rhythms and Mood Disorders: Are the Phenomena and Mechanisms Causally Related? Front Psychiatry. 2015;6:118.
12.	Nutt D. The role of Dopamine and Norepinephrine in Depression and Antidepressant Treatment. J Clin Psychiatry. 2006;67:3-8.
13.	Williamson JA, O'Hara MW, Stuart S, Hart KJ, Watson D. Assessment of postpartum depressive symptoms: the importance of somatic symptoms and irritability. Assessment. 2015;22(3):309-18.
14.	Ngai FW, Ngu SF. Predictors of maternal and paternal depressive symptoms at postpartum. J Psychosom Res. 2015;78(2):156-61.
15.	Freeman EW, Sammel MD, Boorman DW, Zhang R. Longitudinal pattern of depressive symptoms around natural menopause. JAMA Psychiatry. 2014;71(1):36-43.
16.	Mauas V, Kopala-Sibley DC, Zuroff DC. Depressive symptoms in the transition to menopause: the roles of irritability, personality vulnerability, and self-regulation. Arch Womens Ment Health. 2014;17(4):279-89.
17.	Garvey MJ, Goodes M, Furlong C, Tollefson GD. Does cold winter weather produce depressive symptoms? Int J Biometeorol. 1988;32(2):144-6.
18.	Shipowick CD, Moore CB, Corbett C, Bindler R. Vitamin D and depressive symptoms in women during the winter: a pilot study. Appl Nurs Res. 2009;22(3):221-5.
19.	Yang AC, Huang NE, Peng CK, Tsai SJ. Do seasons have an influence on the incidence of depression? The use of an internet search engine query data as a proxy of human affect. PloS one. 2010;5(10):e13728.
20.	McGuffin P, Katz R, Watkins S, Rutherford J. A hospital-based twin register of the heritability of DSM-IV unipolar depression. Arch Gen Psychiatry. 1996;53(2):129-36.

21.   Farmer A, Harris T, Redman K, Sadler S, Mahmood A, McGuffin P. Cardiff depression study. A sib-pair study of life events and familiality in major depression. Br J Psychiatry. 2000;176:150-5.
22.   Kendler KS, Prescott CA. A population-based twin study of lifetime major depression in men and women. Arch Gen Psychiatry. 1999;56(1):39-44.
23.   Monroe SM, Slavich GM, Gotlib IH. Life stress and family history for depression: the moderating role of past depressive episodes. Journal of psychiatric research. 2014;49:90-5.
24.   ROBERT M.A HIRSCHFELD MMW. RISK FACTORS FOR MAJOR

DEPRESSION AND BIPOLAR

DISORDER. American college of NEUROPSYCHOPHARMACOLOGY. 2002:10.
25.   Glaesmer H, Riedel-Heller S, Braehler E, Spangenberg L, Luppa M. Age- and gender-specific prevalence and risk factors for depressive symptoms in the elderly: a population-based study. International psychogeriatrics / IPA. 2011;23(8):1294-300.
26.   Pahkala K, Kivela SL, Laippala P. Social and environmental factors and major depression in old age. Z Gerontol. 1991;24(1):17-23.
27.   Psychcentral. Risk Factors for Depression 2013 [2015-09-23]. Available from: http://psychcentral.com/lib/risk-factors-for-depression/58/.
28.   Patten SB, Wang JL, Williams JV, Currie S, Beck CA, Maxwell CJ, et al. Descriptive epidemiology of major depression in Canada. Can J Psychiatry. 2006;51(2):84-90.
29.   Luke S, Salihu HM, Alio AP, Mbah AK, Jeffers D, Berry EL, et al. Risk factors for major antenatal depression among low-income African American women. J Womens Health (Larchmt). 2009;18(11):1841-6.
30.   Weaver A, Himle JA, Taylor RJ, Matusko NN, Abelson JM. Urban vs Rural Residence and the Prevalence of Depression and Mood Disorder Among African American Women and Non-Hispanic White Women. JAMA Psychiatry. 2015;72(6):576-83.
31.   Kim JM, Stewart R, Shin IS, Yoon JS, Lee HY. Lifetime urban/rural residence, social support and late-life depression in Korea. Int J Geriatr Psychiatry. 2004;19(9):843-51.
32.   Dunlop DD, Song J, Lyons JS, Manheim LM, Chang RW. Racial/ethnic differences in rates of depression among preretirement adults. Am J Public Health. 2003;93(11):1945-52.
33.   Wu Z, Noh S, Kaspar V, Schimmele CM. Race, ethnicity, and depression in Canadian society. J Health Soc Behav. 2003;44(3):426-41.
34.   Cheasty M, Clare AW, Collins C. Relation between sexual abuse in childhood and adult depression: case-control study. Bmj. 1998;316(7126):198-201.
35.   Lindert J, von Ehrenstein OS, Grashow R, Gal G, Braehler E, Weisskopf MG. Sexual and physical abuse in childhood is associated with depression and anxiety over the life course: systematic review and meta-analysis. International journal of public health. 2014;59(2):359-72.
36.   Shapero BG, Black SK, Liu RT, Klugman J, Bender RE, Abramson LY, et al. Stressful life events and depression symptoms: the effect of childhood emotional abuse on stress reactivity. Journal of clinical psychology. 2014;70(3):209-23.
37.   Slavich GM, Monroe SM, Gotlib IH. Early parental loss and depression history: associations with recent life stress in major depressive disorder. Journal of psychiatric research. 2011;45(9):1146-52.
38.   McQuaid RJ, Bombay A, McInnis OA, Matheson K, Anisman H. Childhood adversity, perceived discrimination, and coping strategies in relation to depressive symptoms among First Nations adults in Canada: The moderating role of unsupportive social interactions from ingroup and outgroup members. Cultur Divers Ethnic Minor Psychol. 2015;21(3):326-36.

39.   Kim TH, Connolly JA, Tamim H. The effect of social support around pregnancy on postpartum depression among Canadian teen mothers and adult mothers in the maternity experiences survey. BMC pregnancy and childbirth. 2014;14:162.

40.   Papadopoulos K, Papakonstantinou D, Montgomery A, Solomou A. Social support and depression of adults with visual impairments. Res Dev Disabil. 2014;35(7):1734-41.

41.   Mai F. Depression in physical illnesses. Psychiatr J Univ Ott. 1989;14(2):354-5.

42.   Roose SP, Glassman AH, Seidman SN. Relationship between depression and other medical illnesses. Jama. 2001;286(14):1687-90.

43.   Eramudugolla R, Wood J, Anstey KJ. Co-morbidity of depression and anxiety in common age-related eye diseases: a population-based study of 662 adults. Frontiers in aging neuroscience. 2013;5:56.

44.   Qian Y, Glaser T, Esterberg E, Acharya NR. Depression and visual functioning in patients with ocular inflammatory disease. American journal of ophthalmology. 2012;153(2):370-8 e2.

45.   Fan H, Yu W, Zhang Q, Cao H, Li J, Wang J, et al. Depression after heart failure and risk of cardiovascular and all-cause mortality: a meta-analysis. Prev Med. 2014;63:36-42.

46.   Ma L, Zhao X, Liu H, Zhu H, Yang W, Qian Y, et al. Antidepression medication improves quality of life in elderly patients with benign prostatic hyperplasia and depression. Int J Clin Exp Med. 2015;8(3):4031-7.

47.   Craig TJ, Van Natta PA. Current medication use and symptoms of depression in a general population. The American journal of psychiatry. 1978;135(9):1036-9.

48.   Patten SB, Williams JV, Love EJ. Depressive symptoms attributable to medication exposure in a medical inpatient population. Can J Psychiatry. 1996;41(10):651-4.

49.   Audrain-McGovern J, Rodriguez D, Kassel JD. Adolescent smoking and depression: evidence for self-medication and peer smoking mediation. Addiction. 2009;104(10):1743-56.

50.   Witkiewitz K, Villarroel NA. Dynamic association between negative affect and alcohol lapses following alcohol treatment. Journal of consulting and clinical psychology. 2009;77(4):633-44.

51.   Mafra D, Fouque D. Lower physical activity and depression are associated with hospitalization and shorter survival in CKD. Clin J Am Soc Nephrol. 2014;9(10):1669-70.

52.   Murillo-Perez L, Rojas-Adrianzen C, Ramos-Torres G, Cardenas-Vicente B, Hernandez-Fernandez W, Larco-Castilla P, et al. [Association between the risk of major depression and low physical activity in peruvian workers studying in universities]. Rev Peru Med Exp Salud Publica. 2014;31(3):520-4.

53.   CDC. Depression 2013 [2015-09-24]. Available from: http://www.cdc.gov/mentalhealth/basics/mental-illness/depression.htm.

54.   Franzen PL, Buysse DJ, Rabinovitz M, Pollock BG, Lotrich FE. Poor sleep quality predicts onset of either major depression or subsyndromal depression with irritability during interferon-alpha treatment. Psychiatry research. 2010;177(1-2):240-5.

55.   Paunio T, Korhonen T, Hublin C, Partinen M, Koskenvuo K, Koskenvuo M, et al. Poor sleep predicts symptoms of depression and disability retirement due to depression. Journal of affective disorders. 2014;172C:381-9.

56.   Coulombe JA, Reid GJ, Boyle MH, Racine Y. Sleep problems, tiredness, and psychological symptoms among healthy adolescents. J Pediatr Psychol. 2011;36(1):25-35.

57.   Sariarslan HA, Gulhan YB, Unalan D, Basturk M, Delibas S. The relationship of sleep problems to life quality and depression. Neurosciences. 2015;20(3):236-42.

58.   Sukegawa T, Itoga M, Seno H, Miura S, Inagaki T, Saito W, et al. Sleep disturbances and depression in the elderly in Japan. Psychiatry and clinical neurosciences. 2003;57(3):265-70.

59.   Mansell W, Colom F, Scott J. The nature and treatment of depression in bipolar disorder: a review and implications for future psychological investigation. Clin Psychol Rev. 2005;25(8):1076-100.

60.   Edward KL, Munro I. Depression and other mental illnesses in the context of workplace efficacy. Journal of psychiatric and mental health nursing. 2008;15(7):605-11.

61.   Jensen LW, Decker L, Andersen MM. Depression and health-promoting lifestyles of persons with mental illnesses. Issues in mental health nursing. 2006;27(6):617-34.

62.   Murrock CJ, Graor CH. Depression, Social Isolation, and the Lived Experience of Dancing in Disadvantaged Adults. Archives of psychiatric nursing. 2016;30(1):27-34.

63.   Saito T, Kai I, Takizawa A. Effects of a program to prevent social isolation on loneliness, depression, and subjective well-being of older adults: a randomized trial among older migrants in Japan. Archives of gerontology and geriatrics. 2012;55(3):539-47.

64.   Arthur HM. Depression, isolation, social support, and cardiovascular disease in older adults. The Journal of cardiovascular nursing. 2006;21(5 Suppl 1):S2-7; quiz S8-9.

65.   Bradvik L, Berglund M. Depressive episodes with suicide attempts in severe depression: suicides and controls differ only in the later episodes of unipolar depression. Arch Suicide Res. 2010;14(4):363-7.

66.   Kleiman EM, Liu RT, Riskind JH. Integrating the interpersonal psychological theory of suicide into the depression/suicidal ideation relationship: a short-term prospective study. Behav Ther. 2014;45(2):212-21.

67.   Leadholm AK, Rothschild AJ, Nielsen J, Bech P, Ostergaard SD. Risk factors for suicide among 34,671 patients with psychotic and non-psychotic severe depression. Journal of affective disorders. 2014;156:119-25.

68.   Polku H, Mikkola TM, Rantakokko M, Portegijs E, Tormakangas T, Rantanen T, et al. Self-reported hearing difficulties and changes in life-space mobility among community-dwelling older adults: a Two-year follow-Up study. BMC geriatrics. 2015;15:121.

69.   Asami Y, Goren A, Okumura Y. Work productivity loss with depression, diagnosed and undiagnosed, among workers in an Internet-based survey conducted in Japan. J Occup Environ Med. 2015;57(1):105-10.

70.   Hysenbegasi A, Hass SL, Rowland CR. The impact of depression on the academic productivity of university students. J Ment Health Policy Econ. 2005;8(3):145-51.

71.   Dewa CS, Thompson AH, Jacobs P. The association of treatment of depressive episodes and work productivity. Can J Psychiatry. 2011;56(12):743-50.

72.   Coleman SM, Katon W, Lin E, Von Korff M. Depression and death in diabetes; 10-year follow-up of all-cause and cause-specific mortality in a diabetic cohort. Psychosomatics. 2013;54(5):428-36.

73.   Zivin K, Yosef M, Miller EM, Valenstein M, Duffy S, Kales HC, et al. Associations between depression and all-cause and cause-specific risk of death: a retrospective cohort study in the Veterans Health Administration. J Psychosom Res. 2015;78(4):324-31.

74.   Mykletun A, Bjerkeset O, Dewey M, Prince M, Overland S, Stewart R. Anxiety, depression, and cause-specific mortality: the HUNT study. Psychosom Med. 2007;69(4):323-31.

75.   Almeida OP, Hankey GJ, Yeap BB, Golledge J, Norman PE, Flicker L. Depression, frailty, and all-cause mortality: a cohort study of men older than 75 years. J Am Med Dir Assoc. 2015;16(4):296-300.

76.   Fan L, Sarnak MJ, Tighiouart H, Drew DA, Kantor AL, Lou KV, et al. Depression and all-cause mortality in hemodialysis patients. Am J Nephrol. 2014;40(1):12-8.

77.   Hayman KJ, Kerse NM, La Grow SJ, Wouldes T, Robertson MC, Campbell AJ. Depression in older people: visual impairment and subjective ratings of health. Optom Vis Sci. 2007;84(11):1024-30.

78.   Ribeiro MV, Hasten-Reiter Junior HN, Ribeiro EA, Juca MJ, Barbosa FT, Sousa-Rodrigues CF. Association between visual impairment and depression in the elderly: a systematic review. Arquivos brasileiros de oftalmologia. 2015;78(3):197-201.

79.   Giloyan A, Harutyunyan T, Petrosyan V. Visual impairment and depression among socially vulnerable older adults in Armenia. Aging & mental health. 2015;19(2):175-81.

80.   Mathew RS, Delbaere K, Lord SR, Beaumont P, Vaegan, Madigan MC. Depressive symptoms and quality of life in people with age- related macular degeneration. Ophthalmic Physiol Opt. 2011;31(4):375-80.

81.   Popescu ML, Boisjoly H, Schmaltz H, Kergoat MJ, Rousseau J, Moghadaszadeh S, et al. Explaining the relationship between three eye diseases and depressive symptoms in older adults. Investigative ophthalmology & visual science. 2012;53(4):2308-13.

82.   Casten RJ, Rovner BW, Tasman W. Age-related macular degeneration and depression: a review of recent research. Current opinion in ophthalmology. 2004;15(3):181-3.

83.   Jampel HD, Frick KD, Janz NK, Wren PA, Musch DC, Rimal R, et al. Depression and mood indicators in newly diagnosed glaucoma patients. American journal of ophthalmology. 2007;144(2):238-44.

84.   Brody BL, Gamst AC, Williams RA, Smith AR, Lau PW, Dolnak D, et al. Depression, visual acuity, comorbidity, and disability associated with age-related macular degeneration. Ophthalmology. 2001;108(10):1893-900; discussion 900-1.

85.   U.S. Department of Health and Human Services NIoHNIoDaDaDaKD. Diabetes in African Americans. Bethesda,

: MD: U.S. Department of Health and Human Services, National Institutes

of Health, 2005.

86.   Yilmaz U, Gokler ME, Unsal A. Dry eye disease and depression-anxiety-stress: A hospital-based case control study in Turkey. Pak J Med Sci. 2015;31(3):626-31.

87.   Sieu N, Katon W, Lin EH, Russo J, Ludman E, Ciechanowski P. Depression and incident diabetic retinopathy: a prospective cohort study. General hospital psychiatry. 2011;33(5):429-35.

88.   Xu X, Zhao X, Qian D, Dong Q, Gu Z. Investigating Factors Associated with Depression of Type 2 Diabetic Retinopathy Patients in China. PloS one. 2015;10(7):e0132616.

89.   Cuijpers P. Combined pharmacotherapy and psychotherapy in the treatment of mild to moderate major depression? JAMA Psychiatry. 2014;71(7):747-8.

90.   Marcus SC, Olfson M. National trends in the treatment for depression from 1998 to 2007. Arch Gen Psychiatry. 2010;67(12):1265-73.

91.   Mulsant BH, Blumberger DM, Ismail Z, Rabheru K, Rapoport MJ. A systematic approach to pharmacotherapy for geriatric major depression. Clin Geriatr Med. 2014;30(3):517-34.

92.   Roose SP, Sackeim HA, Krishnan KR, Pollock BG, Alexopoulos G, Lavretsky H, et al. Antidepressant pharmacotherapy in the treatment of depression in the very old: a randomized, placebo-controlled trial. The American journal of psychiatry. 2004;161(11):2050-9.

93.   Schulberg HC, Block MR, Madonia MJ, Rodriguez E, Scott CP, Lave J. Applicability of clinical pharmacotherapy guidelines for major depression in primary care settings. Arch Fam Med. 1995;4(2):106-12.

94.   Cuijpers P, van Straten A, Andersson G, van Oppen P. Psychotherapy for depression in adults: a meta-analysis of comparative outcome studies. Journal of consulting and clinical psychology. 2008;76(6):909-22.

95.   Gum AM, Hirsch A, Dautovich ND, Ferrante S, Schonfeld L. Six-month utilization of psychotherapy by older adults with depressive symptoms. Community mental health journal. 2014;50(7):759-64.

96.   Nierenberg AA, Petersen TJ, Alpert JE. Prevention of relapse and recurrence in depression: the role of long-term pharmacotherapy and psychotherapy. J Clin Psychiatry. 2003;64 Suppl 15:13-7.

97.   Lu CY, Roughead E. New users of antidepressant medications: first episode duration and predictors of discontinuation. Eur J Clin Pharmacol. 2012;68(1):65-71.

98.   Dwight-Johnson M, Sherbourne CD, Liao D, Wells KB. Treatment preferences among depressed primary care patients. J Gen Intern Med. 2000;15(8):527-34.

99.   Moradveisi L, Huibers M, Renner F, Arntz A. The influence of patients' preference/attitude towards psychotherapy and antidepressant medication on the treatment of major depressive disorder. Journal of behavior therapy and experimental psychiatry. 2014;45(1):170-7.

100.   Choices.ca DI. Informed choices about depression 2016 [January 2016]. Available from: http://depression.informedchoices.ca/types-of-treatment/counseling-or-therapy/how-much-does-therapy-or-counseling-cost/.

101.   association CCaP. Counselling and Psychotherapy cost 2016 [January 2016]. Available from: http://www.talkingcanhelp.ca/en/what-is-therapy/cost/.

102.   Johnston S, Liddy C, Mill K, Irving H. Building the evidence base for chronic disease self-management support interventions across Canada. Canadian journal of public health = Revue canadienne de sante publique. 2012;103(6):e462-7.

103.   Nakagawa-Kogan H, Garber A, Jarrett M, Egan KJ, Hendershot S. Self-management of hypertension: predictors of success in diastolic blood pressure reduction. Research in nursing & health. 1988;11(2):105-15.

104.   Lorig KR, Holman H. Self-management education: history, definition, outcomes, and mechanisms. Annals of behavioral medicine : a publication of the Society of Behavioral Medicine. 2003;26(1):1-7.

105.   Juliet M. Corbin AS. Unending Work and Care: Managing Chronic Illness at Home. Series JBSaBS, editor1988. 384 p.

106.   Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. JAMA. 2002;288(19):2469-75.

107.   J FF. Self-Management Support Interventions for Persons With Chronic Disease: An Evidence-Based Analysis. 2013 september 2013. Report No.

108.   Pfaeffli Dale L, Dobson R, Whittaker R, Maddison R. The effectiveness of mobile-health behaviour change interventions for cardiovascular disease self-management: A systematic review. European journal of preventive cardiology. 2015.

109.   Waxman R, Woodburn H, Powell M, Woodburn J, Blackburn S, Helliwell P. FOOTSTEP: a randomized controlled trial investigating the clinical and cost effectiveness of a patient self-management program for basic foot care in the elderly. Journal of clinical epidemiology. 2003;56(11):1092-9.

110.   Miaskowski C, Dodd M, West C, Schumacher K, Paul SM, Tripathy D, et al. Randomized clinical trial of the effectiveness of a self-care intervention to improve cancer pain management. Journal of clinical oncology : official journal of the American Society of Clinical Oncology. 2004;22(9):1713-20.

111.   Cote J, Godin G, Ramirez-Garcia P, Rouleau G, Bourbonnais A, Gueheneuc YG, et al. Virtual intervention to support self-management of antiretroviral therapy among people living with HIV. Journal of medical Internet research. 2015;17(1):e6.

112.   Millard T, Elliott J, Girdler S. Self-management education programs for people living with HIV/AIDS: a systematic review. AIDS patient care and STDs. 2013;27(2):103-13.

113.   McCusker J, Cole MG, Yaffe M, Strumpf E, Sewitch M, Sussman T, et al. A randomized trial of a depression self-care toolkit with or without lay telephone coaching for primary care patients with chronic physical conditions. Gen Hosp Psychiatry. 2015;37(3):257-65.

114.   Ludman EJ, Peterson D, Katon WJ, Lin EH, Von Korff M, Ciechanowski P, et al. Improving confidence for self care in patients with depression and chronic illnesses. Behavioral medicine. 2013;39(1):1-6.

115.   Dozeman E, van Schaik DJ, van Marwijk HW, Stek ML, Beekman AT, van der Horst HE. Feasibility and effectiveness of activity-scheduling as a guided self-help intervention for the prevention of depression and anxiety in residents in homes for the elderly: a pragmatic randomized controlled trial. International psychogeriatrics / IPA. 2011;23(6):969-78.

116.   Johansson R, Ekbladh S, Hebert A, Lindstrom M, Moller S, Petitt E, et al. Psychodynamic guided self-help for adult depression through the internet: a randomised controlled trial. PloS one. 2012;7(5):e38021.

117.   Coventry PA, Gellatly JL. Improving outcomes for COPD patients with mild-to-moderate anxiety and depression: a systematic review of cognitive behavioural therapy. British journal of health psychology. 2008;13(Pt 3):381-400.

118.   Brody BL, Roch-Levecq AC, Kaplan RM, Moutier CY, Brown SI. Age-related macular degeneration: self-management and reduction of depressive symptoms in a randomized, controlled study. Journal of the American Geriatrics Society. 2006;54(10):1557-62.

119.   Brody BL, Roch-Levecq AC, Thomas RG, Kaplan RM, Brown SI. Self-management of age-related macular degeneration at the 6-month follow-up: a randomized controlled trial. Archives of ophthalmology. 2005;123(1):46-53.

120.   Rovner BW, Casten RJ. Preventing late-life depression in age-related macular degeneration. The American journal of geriatric psychiatry : official journal of the American Association for Geriatric Psychiatry. 2008;16(6):454-9.

121.   Unutzer J, Katon W, Callahan CM, Williams JW, Jr., Hunkeler E, Harpole L, et al. Depression treatment in a sample of 1,801 depressed older adults in primary care. J Am Geriatr Soc. 2003;51(4):505-14.

122.   Dezetter A, Duhoux A, Menear M, Roberge P, Chartrand E, Fournier L. Reasons and Determinants for Perceiving Unmet Needs for Mental Health in Primary Care in Quebec. Can J Psychiatry. 2015;60(6):284-93.

123.   Clement S, Schauman O, Graham T, Maggioni F, Evans-Lacko S, Bezborodovs N, et al. What is the impact of mental health-related stigma on help-seeking? A systematic review of quantitative and qualitative studies. Psychol Med. 2015;45(1):11-27.

124.   Rovner BW, Casten RJ, Hegel MT, Massof RW, Leiby BE, Ho AC, et al. Low vision depression prevention trial in age-related macular degeneration: a randomized clinical trial. Ophthalmology. 2014;121(11):2204-11.

125.   Gellatly J, Bower P, Hennessy S, Richards D, Gilbody S, Lovell K. What makes self-help interventions effective in the management of depressive symptoms? Meta-analysis and meta-regression. Psychol Med. 2007;37(9):1217-28.

126.   Rovner BW, Casten RJ, Murchison AP, Ho AC, Henderer J, Haller JA. Depression and Memory Loss in African Americans with Diabetic Retinopathy. Journal of the American Geriatrics Society. 2015;63(6):1249-51.

127.   Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med. 2001;16(9):606-13.

128.   Katzman R, Brown T, Fuld P, Peck A, Schechter R, Schimmel H. Validation of a short Orientation-Memory-Concentration Test of cognitive impairment. Am J Psychiatry. 1983;140(6):734-9.

129.   CONSORT: Transparent Reporting of Trials 2010 [cited 2016 January 12]. Available from: http://www.consort-statement.org/.

130.   Bilsker D, Paterson R. Antidepressant Skills Workbook: British Columbia Mental Health and Addiction Services; 2005 [cited 2016 January 13]. Available from: http://www.comh.ca/antidepressant-skills/adult/resources/index-asw.cfm.

131.   Spitzer RL, Kroenke K, Williams JB, Lowe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med. 2006;166(10):1092-7.

132.   Baker PS, Bodner EV, Allman RM. Measuring life-space mobility in community-dwelling older adults. Journal of the American Geriatrics Society. 2003;51(11):1610-4.

133.   Williams GC, Freedman ZR, Deci EL. Supporting autonomy to motivate patients with diabetes for glucose control. Diabetes Care. 1998;21(10):1644-51.

134.   Moore M, Ali S, Stuart B, Leydon GM, Ovens J, Goodall C, et al. Depression management in primary care: an observational study of management changes related to PHQ-9 score for depression monitoring. Br J Gen Pract. 2012;62(599):e451-7.

135.   Lowe B, Unutzer J, Callahan CM, Perkins AJ, Kroenke K. Monitoring depression treatment outcomes with the patient health questionnaire-9. Med Care. 2004;42(12):1194-201.

136.   Barnett AG, van der Pols JC, Dobson AJ. Regression to the mean: what it is and how to deal with it. Int J Epidemiol. 2005;34(1):215-20.

Appendices

1. Patient Baseline Interview

Instructions to interviewer:

Please note that only text in **bold** should be read to patients. Additional questions that may be needed for probing are *italicized*.

For any question where a preset response was not selected, choose the "other code" that applies (N.B. these codes are to be used as little as possible; before using them, try to probing respondent more for an answer):

Not applicable (NA): 77
Don't know (DK): 88
Refused (R): 9

Table of Contents

Thank you for agreeing to this interview. All the information you provide will be kept entirely confidential. If you feel uncomfortable answering any of the questions, let me know and we can skip it. To ensure that we have enough time to get through all the questions, please use only the answer choices provided.

ISURG1: INJECTION TODAY?

1. YES   2. NO

Section A: Medications

MED1: First, let's talk about your prescribed medications.

Must be <u>current</u> medications, i.e. taken during the last week.

List the medications in the following chart. If patient has a print-out list and allows you to keep it, then you do not need to list the medications here.

If NONE, skip to Section C

Name	# of times/day *or* # of times/week
1a.	
1b.	
1c.	
1d.	
1e.	
1f.	
1g.	

Section B: Medications and Adherence

MED 2. Considering all your prescription medicines…

MED2a.   During the past week, did you ever forget to take any of these medicines?

0 No

1 Yes

88 DK

Refused

MED2b. During the past week, were you careless at times about taking any of these medicines?

Were there times when you couldn't be bothered to take them?

0 No

1 Yes

88 DK

Refused

MED2c. During the past week, if you felt better did you sometimes not take or entirely stop taking any of these medicines?

0 No

1 Yes

88 DK

Refused

MED2d. During the past week, if you felt worse when you took any of these medicines, did you stop taking them?

0 No

1 Yes

88 DK

99 Refused

Section C: General Health Status

The next question asks for your view about your health.

GHS. In general, would you say your health is…

0 **excellent?**

1 **very good?**

2 **good?**

3 **fair?**

4 **poor?**

88 DK

Refused

Section D: GAD-7

Over <u>the last 2 weeks</u>, how often have you been bothered by any of the following problems? For each item, please tell me if you have not been bothered at all, been bothered for several days, been bothered more than half the days, or been bothered nearly every day.

Remind respondents of the choices when necessary

If patient says "1 day" mark as "several days".

	Problem	Not at all	Several days	More than half the days	Nearly every day	Other: 88 DK 99 R
1	**Feeling nervous, anxious, or on edge**	0	1	2	3	
2	**Not being able to stop or control worrying**	0	1	2	3	
3	**Worrying too much about different things**	0	1	2	3	
4	**Trouble relaxing**	0	1	2	3	
5	**Being so restless that it is hard to sit still**	0	1	2	3	
6	**Becoming easily annoyed or irritable**	0	1	2	3	
7	**Feeling afraid as if something awful might happen**	0	1	2	3	

Section E: Everyday Activities

Now I would like to ask you about your daily activities. Please tell me how many times you may have engaged in each activity in the past week.

	In the past week, how many times did you…	# of times	Other: 99 R
1	**Visit with family, relatives, friends, or neighbours in person?**		
2	**Have a telephone conversation with family, relatives, friends, or neighbours?**		
3	**Contact family, relatives, friends, or neighbours through electronic means other than telephone? For example, email, text messaging, or Facebook.**		
4	**Attend a religious service, such as church or synagogue or mosque?**		
5	**Participate in a social or recreational group activity?**		
6	**Take a day trip or overnight trip?**		
7	**Go to a concert, play, or art exhibition?**		

	How many DAYS *(not "times"!)* **in the past week, did you…**	# of DAYS	Other: 99 R
8	**Spend time on hobbies such as collecting or handiwork?**		
9	**Spend time reading, writing (***including time on the computer but not work-related***), or listening to music?**		
10	**Do light housework or gardening?**		
11	**Do heavy housework or yard work?**		

Do you currently do volunteer work?

0 No   ]→go to next section

1 Yes

88 DK]→go to next section

      ]→go to next section

12a. How many days in the last week did you engage in volunteer work?

_____ days

88 DK

99 R

13. Do you ever use the Internet, for example, checking your email, finding information?

0 No   ] → Go to Section G

1 Yes

R   ] → Go to Section G

13a. how often do you use the Internet in a typical month?

1   At least once a day

2   At least once a week (but not every day)

3   At least once a month (but not every week)

4   Less than once a month

88 DK

99 R

Section F: Smoking

I would like to ask you some questions about smoking.

SMK1. Have you ever smoked (that includes cigars, pipes or cigarettes)?

0 No   → go to next section

1 Yes

99 Refused → go to next section

SMK2. Do you currently smoke any of these?

0 No   → go to next section

1 Yes

99 Refused → go to next section

SMK3. Which ones?

Multiple answers permitted, probe to record all possible answers.

0 cigarettes

1 pipes   → go to next section

2 cigars → go to next section

3 other → go to next section

99 refused → go to next section

SMK4. How many cigarettes a day did you smoke during the last week?

_____ cigarettes / day

99 Refused

88 Don't know

Section G: Life Space Questionnaire

LS1. During the past 4 weeks but not including today, have you been to another room of your home besides the room where you sleep?

0. No (SKIP TO QUESTION 2)

1. Yes

2. Refuse (SKIP TO QUESTION 2)

LS1a. If yes, how often did you go to another room besides the room where you sleep?

1. Less than 1 day / week

        2. 1-3 days / week

        3. 4-6 days / week

        4. Daily

LS1b. Did you use technical aids or equipment to get there (for example a cane or a walker)?

0. No

1. Yes

2. Refuse or Don't Know

LS1c. Did you need help from another person to get there?

0. No

1. Yes

2. Refuse or Don't Know

LS2. During the past 4 weeks, have you been to an area outside your home such as your porch, deck, patio, hallway (of an apartment building) or garage in your own yard, or driveway?

0. No (SKIP TO QUESTION 3)

1. Yes

2. Refuse (SKIP TO QUESTION 3)

LS2a. If yes, how often did you go there…?

1. Less than 1 day / week

        2. 1-3 days / week

        3. 4-6 days / week

        4. Daily

LS2b. Did you use technical aids or equipment to get there (for example a cane or a walker)?

0. No

1. Yes

2. Refuse or Don't Know

LS2c. Did you need help from another person to get there?

0. No

1. Yes

2. Refuse or Don't Know

LS3. During the past 4 weeks, have you been to places in your neighbourhood, other than your own yard or apartment building?

0. No (SKIP TO QUESTION 4)

1. Yes

2. Refuse (SKIP TO QUESTION 4)

LS3a. If yes, how often did you go there…?

1. Less than 1 day / week

2. 1-3 days / week

3. 4-6 days / week

4. Daily

LS3b. Did you use technical aids or equipment to get there (for example a cane or a walker)?

0. No

1. Yes

2. Refuse or Don't Know

LS3c. Did you need help from another person to get there?

0. No

1. Yes

2. Refuse or Don't Know

LS4. During the past 4 weeks, have you been to places outside your own neighbourhood but within your town?

0. No (SKIP TO QUESTION 5)

1. Yes

2. Refuse (SKIP TO QUESTION 5)

LS4a. If yes, how often did you go there…?

1. Less than 1 day / week

2. 1-3 days / week

3. 4-6 days / week

4. Daily

LS4b. Did you use technical aids or equipment to get there (for example a cane or a walker)?

0. No

1. Yes

2. Refuse or Don't Know

LS4c. Did you need help from another person …?

0. No

1. Yes

2. Refuse or Don't Know

LS5. During the past 4 weeks, have you been to places outside your town?

0. No (SKIP TO NEXT SECTION)

1. Yes

2. Refuse (SKIP TO NEXT SECTION)

LS5a. If yes, how often did you go there…?

1. Less than 1 day / week

2. 1-3 days / week

3. 4-6 days / week

4. Daily

LS5b. Did you use technical aids or equipment to get there (for example a cane or a walker)?

0. No

1. Yes

2. Refuse or Don't Know

LS5c. Did you need help from another person to get there?

0. No

1. Yes

2. Refuse or Don't Know

Section H: Self-Efficacy

I am going to read to you some statements that people sometimes make when they talk about their mood. For each statement, please indicate how much you agree or disagree with each statement as it applies to you personally.

Repeat choices whenever necessary.

If respondent answers don't know, probe more:

You don't know because you don't understand?Because you're not sure?

Try to narrow down what it is in the statement that makes the patient not know.

	Disagree strongly	Disagree	Agree	Agree strongly	Don't Know	Refuse
I am able to carry out daily activities that can keep my mood positive	0	1	2	3	88	99
I feel confident that I can recognize situations that will bring my mood down	0	1	2	3	88	99
I feel able to meet the challenges of learning and practicing new skills to control my mood	0	1	2	3	88	99
I am capable of stopping my mood from becoming negative.	0	1	2	3	88	99

Section I: Social Networks

FAMILY/PARTNER: Considering the people to whom you are related either by birth or marriage/partnership . . .

LUB1. How many relatives do you see or hear from at least once a month?

0 =none   1 =one   2 = two   3 = three or four   4 = five thru eight   5 = nine or more

LUB2. How many relatives do you feel close to such that you could call on them for help?

0 =none   1 =one   2 = two   3 = three or four   4 = five thru eight   5 = nine or more

LUB3. How many relatives do you feel at ease with that you can talk about private matters?

0 =none   1 =one   2 = two   3 = three or four   4 = five thru eight   5 = nine or more

FRIENDSHIPS: Considering all of your friends including those who live in your neighborhood.

LUB4. How many of your friends do you see or hear from at least once a month?

0 =none   1 =one   2 = two   3 = three or four   4 = five thru eight   5 = nine or more

LUB5. How many friends do you feel close to such that you could call on them for help?

0 =none   1 =one   2 = two   3 = three or four   4 = five thru eight   5 = nine or more

LUB6. How many friends do you feel at ease with that you can talk about private matters?

0 =none   1 =one   2 = two   3 = three or four   4 = five thru eight   5 = nine or more

Section J: Sociodemographics

Next, I would like to ask some general questions about you.

SOC1: What is your marital status?

0 married?

1 living common-law?

2 widowed?

3 separated?

4 divorced?

5 single, never married?

99 Refused

SOC2: How many years of education did you complete? _____

99 Refused

SOC3: Gender (OBSERVE)

   0   Male

   1   Female

SOC4: Race (OBSERVE)

   0 White

   1 Noir

   2 Other (Specify)

SOC5: Address:

_____

      _____

_____

SOC6: Telephone Number Where We Can Reach You Over Next 2 Months

              _____

SOC7: Secondary Telephone Number (Optional)

              _____

Section K: Health Conditions

HEALTH1: Has a physician ever told you that you have arthritis?

      0. NO

      1. YES

      2. DON`T KNOW OR REFUSE

HEALTH2: Has a physician ever told you that you have asthma?

      0. NO

      1. YES

      2. DON`T KNOW OR REFUSE

HEALTH3: Has a physician ever told you that you have emphysema or chronic obstructive pulmonary disorder?

      0. NO

      1. YES

      2. DON`T KNOW OR REFUSE

HEALTH4: Has a physician ever told you that you have diabetes?

      0. NO

      1. YES

      2. DON`T KNOW OR REFUSE

HEALTH5: Has a physician ever told you that you have hypertension or high blood pressure?

      0. NO

      1. YES

2. DON`T KNOW OR REFUSE

HEALTH6: Has a physician ever told you that you have peripheral artery disease or intermittent claudication?

    0. NO

    1. YES

    2. DON`T KNOW OR REFUSE

HEALTH7: Has a physician ever told you that you have heart disease (angina, atherosclerosis, arrhythmia, congestive heart failure, heart attack, coronary artery disease, atrial fibrillation, etc.)?

    0. NO

    1. YES

    2. DON`T KNOW OR REFUSE

HEALTH8: Has a physician ever told you that you had a stroke?

    0. NO

    1. YES

    2. DON`T KNOW OR REFUSE

HEALTH9: Has a physician ever told you that you have Parkinson's disease?

    0. NO

    1. YES

    2. DON`T KNOW OR REFUSE

HEALTH10: Has a physician ever told you that you have impaired hearing?

    0. NO

    1. YES

    2. DON`T KNOW OR REFUSE

HEALTH11: Has a physician ever told you that you have depression?

       0. NO

       1. YES

       2. DON`T KNOW OR REFUSE

HEALTH12: Has a physician ever told you that you have a back problem?

       0. NO

       1. YES

       2. DON`T KNOW OR REFUSE

HEALTH13: Has a physician ever told you that you fractured your hip?

       0. NO

       1. YES

       2. DON`T KNOW OR REFUSE

LV1: Are you aware of the existence of low vision rehabilitation agencies in Montreal like CNIB, INLB, or MAB-Mackay?

0. NO   (END OF QUESTIONNAIRE)

       1. YES

       2. DON`T KNOW OR REFUSE   (END OF QUESTIONNAIRE)

LV2: Have you ever visited one of these agencies?

       0. NO

       1. YES

       2. DON`T KNOW OR REFUSE

END OF QUESTIONNAIRE FOR PARTICIPANT

Section L: Vision and Eye Disease

INTERVIEWER: Please measure visual acuity and take the other information from the medical chart.

EYE1: What is the binocular habitual visual acuity at 2 meters (letters correct)?

_____

EYE2: What type of eye disease does the person have?

1 dry AMD

2 wet AMD

3 both types of AMD

4 not known

5 diabetic retinopathy

EYE3: What was the first date of diagnosis of late-stage AMD or DR?

_____MM/DD/YY

EYE4: Give all current eye diseases in addition to that stated in EYE2 (only choose 1 at a time).

1. un-operated cataract

2. diabetic retinopathy

3. glaucoma

4. corneal disease

5. blepharitis

6. posterior vitreous detachment

7. ocular hypertension

8. none

9. AMD

EYE5: Give all current eye diseases in addition to AMD (only choose 1 at a time).

1. un-operated cataract

2. diabetic retinopathy

3. glaucoma

4. corneal disease

5. blepharitis

6. posterior vitreous detachment

7. ocular hypertension

8. none

9. AMD

EYE6: Give all current eye diseases in addition to AMD (only choose 1 at a time).

1. un-operated cataract

2. diabetic retinopathy

3. glaucoma

4. corneal disease

5. blepharitis

6. posterior vitreous detachment

7. ocular hypertension

8. none

9. AMD

Section M: Trial Arm

ARM : Which group is the person in?

0. Control (Delayed Intervention)

1. Experimental (Immediate Intervention)

2. Follow-up questionnaire

Instructions to interviewer:

Please note that only text in **bold** should be read to patients. Additional questions that may be needed for probing are *italicized.*

For any question where a preset response was not selected, choose the "other codes" that applies (N.B. these codes are to be used as little as possible; before using them, try to probing respondent more for an answer):

Not applicable (NA): 77

Don't know (DK): 88

Refused (R): 99

Contents:

Section A: Health Status

Following standard greeting and introduction:

This is our last interview for this study. It will take about 30 minutes. Some of the questions are similar to questions we have asked you previously at the start of the study.

The first questions ask for your view about your health.

If respondent answers don't know, probe more:

You don't know because you don't understand? Do you have difficulty remembering or assessing? When was the last time you did … or felt …?

GHS: Compared to 2 months ago, how would you rate your health in general now?

0 much better now than 2 months ago

1 somewhat better now than 2 months ago

2 about the same

3 somewhat worse than 2 months ago

4 much worse than 2 months ago

88 DK

99 R

Section B: PHQ-9

Now a few questions on your mood:

Over the last 2 weeks, how often have you been bothered by any of the following problems? For each item, please tell me if you have not been bothered at all, if you have been bothered for several days, for more than half the days, or been bothered nearly every day.

Remind respondents of the choices and timeframe when necessary.

If patient says "1 day" mark as "several days".

	Problem	Not at all	Several days	More than half the days	Nearly every day	Other: 88 DK 99 R
a	**Little interest or pleasure in doing things**	0	1	2	3	
b	**Feeling down, depressed, or hopeless**	0	1	2	3	
c	**Trouble falling or staying asleep, or sleeping too much**	0	1	2	3	
d	**Feeling tired or having little energy**	0	1	2	3	
e	**Poor appetite or overeating**	0	1	2	3	
f	**Feeling bad about yourself – or that you are a failure or have let yourself or your family down**	0	1	2	3	
g	**Trouble concentrating on things, such as reading the newspaper or watching television**	0	1	2	3	
h	**Moving or speaking so slowly that other people could have noticed? Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual**	0	1	2	3	
i	**Thoughts that you would be better off dead or of hurting yourself in some way**	0	1*	2*	3*	

ONLY ASK j, k, l if response to 1i is 1, 2, or 3

j. **Do you feel these thoughts are something you will act on?**

      0 N   ] → skip to Q2

      1 Y

88 DK   ] → skip to Q2

99 R   ] → skip to Q2

k. **Would it be ok for us to let your family doctor know that you have been having these feelings and thoughts?**

0 N

1 Y

l. **I would like a psychologist involved with the study to speak with you. Would it be ok for me to arrange for you to see the doctor in the next few days?**

0 N

1 Y

I would also like to offer you some telephone contact numbers in case these feelings and thoughts get worse and you need help immediately.

You can call Suicide Action Montreal's hotline at 514-723-4000 or 1-866-277-3553 when you are outside of Montreal.

m. What is the patient's total score? _____

*If score is 20 or more, read 1.n and then Q2.

1n. Based on your answers, you may benefit from professional help. Would it be ok for us to let your family doctor know about your depressed mood?

0 N   ] → **that's ok, but I would just like to encourage you to speak to a medical professional about your mood when you are ready to do so.**

1 Y   ] → **OK great. I'll make sure he/she gets the information.**

I would also like to offer you a telephone contact number in case these feelings and thoughts get worse and you need help immediately.

Offer emergency contact numbers:

You can call Suicide Action Montreal's hotline at 514-723-4000 or 1-866-277-3553 when you are outside of Montreal.

Think about all the problems that you told me about [list problems that the patient had from Q1]. **How difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?**

0 **Not difficult at all**

1 **Somewhat difficult**

2 **Very difficult**

3 **Extremely difficult**

77 NA

88 DK

99 R

Section C: GAD-7

Over the last 2 weeks, how often have you been bothered by any of the following problems? For each item, please tell me if you have not been bothered at all, been bothered for several days, been bothered more than half the days, or been bothered nearly every day.

Remind respondents of the choices when necessary

If patient says "1 day" mark as "several days".

	Problem	Not at all	Several days	More than half the days	Nearly every day	Other: 88 DK 99 R
a	**Feeling nervous, anxious, or on edge**	0	1	2	3	
b	**Not being able to stop or control worrying**	0	1	2	3	
c	**Worrying too much about different things**	0	1	2	3	
d	**Trouble relaxing**	0	1	2	3	
e	**Being so restless that it is hard to sit still**	0	1	2	3	
f	**Becoming easily annoyed or irritable**	0	1	2	3	
g	**Feeling afraid as if something awful might happen**	0	1	2	3	

Section D: Change Questions

Next, I'd like to ask you about changes you may have made in your daily life.

Since participating in this project, have you tried to change something in your daily life to help you feel better?

0 No   → **That's fine.** Skip to Section E

1 Yes

99 R   → skip to Section E

Can you please tell me what these changes that you tried to make were?
PROBE: **Anything else you tried to change or changed to help you feel better?**

	No	Yes	DK	R
Your own personal care, for example getting dressed and washed every day, eating a more healthy diet?	0	1	88	99
Being more physically active?	0	1	88	99
Small chores, like paying bills, housecleaning, grocery shopping?	0	1	88	99
Involvement with your family and friends?	0	1	88	99
Making time for personally rewarding activities, like taking time for hobbies or activities that you enjoy?	0	1	88	99
Trying to set realistic goals?	0	1	88	99
Thinking realistically?	0	1	88	99
Trying to solve daily problems effectively?	0	1	88	99
Remembering to take your prescribed medications?	0	1	88	99
Using relaxation?	0	1	88	99
Something else? Specify:	0	1	88	99

Section E: Medication and Adherence

List all current prescription medications in the following chart.

If NONE, skip to Section F

Name	# of times/day *or* # of times/week
1a.	
1b.	
1c.	
1d.	
1e.	
1f.	
1g.	

2   Now, if we consider all your prescription medicines   SKIP IF NO MEDS ARE TAKEN AT ALL

a.   During the past week, did you ever forget to take any of these medicines?

0 N

1 Y

88 DK

99 R

During the past week, were you careless at times about taking any of these medicines?

Were there times when you couldn't be bothered to take them?

0 N

1 Y

88 DK

99 R

During the past week, if you felt better did you sometimes not take or entirely stop taking any of these medicines?

0 N

1 Y

88 DK

99 R

During the past week, if you felt worse when you took any of these medicines, did you stop taking them?

0 N

1 Y

88 DK

99 R

Section F: Smoking

Now I'd like to ask some questions about smoking.

Do you currently smoke cigarettes?

0 No → go to SECTION G

1 Yes

99 R → go to SECTION G

How many cigarettes a day did you smoke during the last week?

_____cigarettes/day   ASK FOR AN AVERAGE

88 DK

99 R

Section G: Life Space Questionnaire

LS1. During the past 4 weeks, have you been to another room of your home besides the room where you sleep?

0. No

1. Yes (SKIP TO QUESTION 2)

99. Refuse (SKIP TO QUESTION 2)

LS1a. If yes, how often did you go to another room besides the room where you sleep?

1. Less than 1 day / week

       2. 1-3 days / week

       3. 4-6 days / week

       4. Daily

LS1b. Did you use technical aids or equipment to get there (for example a cane or a walker)?

0. No

1. Yes

99. Refuse or Don't Know

LS1c. Did you need help from another person to get there?

0. No

1. Yes

99. Refuse or Don't Know

LS2. During the past 4 weeks, have you been to an area outside your home such as your porch, deck, patio, hallway (of an apartment building) or garage in your own yard, or driveway?

0. No

1. Yes (SKIP TO QUESTION 3)

99. Refuse (SKIP TO QUESTION 3)

LS2a. If yes, how often did you go there…?

1. Less than 1 day / week

2. 1-3 days / week

3. 4-6 days / week

4. Daily

LS2b. Did you use technical aids or equipment to get there (for example a cane or a walker)?

0. No

1. Yes

99. Refuse or Don't Know

LS2c. Did you need help from another person to get there?

0. No

1. Yes

99. Refuse or Don't Know

LS3. During the past 4 weeks, have you been to places in your neighbourhood, other than your own yard or apartment building?

0. No
1. Yes (SKIP TO QUESTION 4)
99. Refuse (SKIP TO QUESTION 4)

LS3a. If yes, how often did you go there…?

1. Less than 1 day / week

2. 1-3 days / week

3. 4-6 days / week

4. Daily

LS3b. Did you use technical aids or equipment to get there (for example a cane or a walker)?

0. No

1. Yes

99. Refuse or Don't Know

LS3c. Did you need help from another person to get there?

0. No

1. Yes

99. Refuse or Don't Know

LS4. During the past 4 weeks, have you been to places outside your own neighbourhood but within your town?

0. No

1. Yes (SKIP TO QUESTION 5)

99. Refuse (SKIP TO QUESTION 5)

LS4a. If yes, how often did you go there…?

1. Less than 1 day / week

2. 1-3 days / week

3. 4-6 days / week

4. Daily

LS4b. Did you use technical aids or equipment to get there (for example a cane or a walker)?

0. No

1. Yes

99. Refuse or Don't Know

LS4c. Did you need help from another person …?

0. No

1. Yes

99. Refuse or Don't Know

LS5. During the past 4 weeks, have you been to places outside your town?

0. No

1. Yes (SKIP TO NEXT SECTION)

99. Refuse (SKIP TO NEXT SECTION)

LS5a. If yes, how often did you go there…?

1. Less than 1 day / week

       2. 1-3 days / week

       3. 4-6 days / week

       4. Daily

LS5b. Did you use technical aids or equipment to get there (for example a cane or a walker)?

0. No

1. Yes

99. Refuse or Don't Know

LS5c. Did you need help from another person to get there?

0. No

1. Yes

99. Refuse or Don't Know

Section H: Everyday Activities

Now I would like to ask you about your daily activities. Please tell me how many times you may have engaged in each activity in the past week.

	In the past week, how many times did you…	# of times	Other: 99 R
1	**Visit with family, relatives, friends, or neighbours in person?**		
2	**Have a telephone conversation with family, relatives, friends, or neighbours?**		
3	**Contact family, relatives, friends, or neighbours through electronic means other than telephone? For example, email, text messaging, or Facebook.**		
4	**Attend a religious service, such as church or synagogue or mosque?**		
5	**Participate in a social or recreational group activity?**		
6	**Take a day trip or overnight trip?**		
7	**Go to a concert, play, or art exhibition?**		

	How many DAYS (not "times"!) **in the past week, did you…**	# of DAYS	Other: 99 R
8	**Spend time on hobbies such as collecting or handiwork?**		
9	**Spend time reading, writing** (*including time on the computer but not work-related*), **or listening to music?**		
10	**Do light housework or gardening?**		
11	**Do heavy housework or yard work?**		

Do you currently do volunteer work?

0 No   ]→go to next section

1 Yes

88 DK]→go to next section

99 R   ]→go to next section

How many days in the last week did you engage in volunteer work?

_____ days

88 DK

99 R

Section I: Social Networks

FAMILY/PARTNER: Considering the people to whom you are related either by birth or marriage/partnership . . .

LUB1. How many relatives do you see or hear from at least once a month?

0 =none   1 =one   2 = two   3 = three or four   4 = five thru eight   5 = nine or more

LUB2. How many relatives do you feel close to such that you could call on them for help?

0 =none   1 =one   2 = two   3 = three or four   4 = five thru eight   5 = nine or more

LUB3. How many relatives do you feel at ease with that you can talk about private matters?

0 =none   1 =one   2 = two   3 = three or four   4 = five thru eight   5 = nine or more

FRIENDSHIPS: Considering all of your friends including those who live in your neighborhood.

LUB4. How many of your friends do you see or hear from at least once a month?

0 =none   1 =one   2 = two   3 = three or four   4 = five thru eight   5 = nine or more

LUB5. How many friends do you feel close to such that you could call on them for help?

0 =none   1 =one   2 = two   3 = three or four   4 = five thru eight   5 = nine or more

LUB6. How many friends do you feel at ease with that you can talk about private matters?

0 =none   1 =one   2 = two   3 = three or four   4 = five thru eight   5 = nine or more

Section J: Self-Efficacy

I am going to read to you some more statements that people sometimes make when they talk about their mood. For each statement, please indicate how much you agree or disagree with each statement as it applies to you personally.

Simplify choices: Do you agree or disagree. If the subject says "I agree" ask "do you agree strongly, or just agree"?

If respondent answers don't know, probe more:

You don't know because you don't understand? Because you're not sure?

Try to narrow down what it is in the statement that makes the patient not know.

	Disagree strongly	Disagree	Agree	Agree strongly	Don't Know	Refuse
I am able to carry out daily activities that can keep my mood positive	0	1	3	4	88	99
I feel confident that I can recognize situations that will bring my mood down	0	1	3	4	88	99
I feel able to meet the challenges of learning and practicing new skills to control my mood	0	1	3	4	88	99
I am capable of stopping my mood from becoming negative.	0	1	3	4	88	99

If Q 4 = "agree" or "strongly agree":

5. **Can you tell me a bit more about what you do to stop your mood from becoming negative?**

Code everything that subject mentions unprompted. Prompt "anything else"?

1. Personal care (e.g., getting dressed washed, eating breakfast, eating a more healthy diet)

2. Being more physically active

3. Small duties, like paying bills, housecleaning, grocery shopping

4. Involvement with your family and friends

5. Making time for personally rewarding activities

6. Setting realistic goals

7. Thinking more realistically

8. Solving problems effectively

9. Remembering to take your prescribed medications

10. Seeking professional counselling or therapy.

11. Applying relaxation techniques

12. Other, specify_____

Section K: Treatments

Now I'd like to ask you about help that you may have received for emotional or mood problems in the last 2 months.

In the last 2 months, have you received information about emotional or mood problems, their treatments, and available services? If the subject asks whether to include information from the study: *Yes, include information from the study, as well as any other information you may have received*

0 No

1 Yes

88 DK

99R

Now please think about therapy or counselling that you may have received for emotional or mood problems in the last 2 months. By therapy or counselling, I mean discussions with a health professional to learn how to deal with your thoughts or behaviours, or to talk through your problems. Did you receive such a form of help?

0 No   ]→ Go to question 3

1 Yes

88 DK   ]→ Go to question 3

99R   ]→ Go to question 3

2a. when did you start this therapy? _____MM/DD/YY

Now, some questions about medications for emotional or mood problems that you might have taken over the last 2 months. Have you taken any medications for emotional or mood problems?

0 N   ]→ Go to question 4

1 Y

88 DK]→ Go to question 4

99 R   ]→ Go to question 4

3a. when did you start this medication? _____ MM/DD/YY

4: Did you have any procedures done on your eyes during the 8-week follow-up period?

> 0. No]→ Go to Next Section
>
> 1. Yes

> **4a: What procedures were done?**
>
> > 1. Anti-VEGF injection (e.g. Lucentis, Avastin)
> >
> > 2. Cataract surgery
> >
> > 3. Laser
> >
> > 4. Trabeculectomy
> >
> > 5. Other _____

_____

Look at the note on the sticker to see in which group is the patient.

For Controls: **I see in your record that you are in the control group and that you will receive the self-care binder by courier at the address you provided when you were recruited. Would it be OK to mail it to you during the next week?**

No   *Let Solmaz know if the answer is no and when to mail

Yes

For Intervention Group:

Please continue with sections L and M.

Section L: Use of self-care tools

Now I'd like to ask you about the self-care materials in the binder that you received at the beginning of the study. Do you remember receiving this blue binder?

Did you look at or use any of the materials in the binder during the last 2 months?

0 No → **That's no problem.** Skip to next section

1 Yes

Do you remember what you looked at or used?? Check all that apply and probe **"Anything else?"**

0 Don't remember

1 Movie

2 Workbook

3 Audio Workbook

4 Mood monitoring

5 Relaxation CD

6 Community resources list

7 Other resources list (websites/books)

8 Medications section

9 Section on eating

10 Other: _____

Some people like to make notes when using the tools in the binder. During the last 2 months, did you make notes in your binder, or in another place?

0 No → **that's a problem.** Skip to SECTION M

1 Yes

Do you remember which sections you wrote in? *Some of the sections included worksheets or places to take notes. We will not be collecting anything you have written, but are interested in finding out if people made notes for themselves.* Check all that apply and probe **"Anything else?"**

0 Don't remember

1 Workbook

2 Mood monitoring

3 Medication sections

4 Other: _____

Did you make notes during the last week?

       0 No → **That's no problem.** Skip to SECTION M

       1 Yes

Which section have you been writing in? Check all that apply and probe **"Anything else?"**

0 Don't remember

1 Workbook

2 Mood monitoring

3 Medication sections

4 Other: _____

Section M: Satisfaction with Care

Now I'd like to ask what you thought about the self-care program we offered you in this study. Please be honest, this will help us improve the program.

Overall, how would you rate the quality of the self-care program you received from this self-care project?

4 Excellent

3 Good

2 Fair

1 Poor

Did the self-care program help you to deal more effectively with your problems?

4 Yes, it helped a great deal

3 Yes, it helped somewhat

2 No, it really didn't help

1 No, it seemed to make things worse

If a friend were in need of similar help, would you recommend this program to him/her?

1 No, definitely not

2 No, I don't think so

3 Yes, I think so

4 Yes, definitely

Please tell me what you liked the most about this program.

_____

And what could be improved?

_____