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ORIGINAL PAPER

The Positive Outlook Study: A Randomised Controlled Trial Evaluating Online Self-Management for HIV Positive Gay Men

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Abstract The aim of this paper was to evaluate the effectiveness of an online self-management program in improving health outcomes and well-being for gay men living with HIV in Australia. The online Positive Outlook Program was based on self-efficacy theory and used a self-management approach to enhance HIV-positive gay men's skills, confidence and abilities to manage the psychosocial issues associated with HIV in daily life. The 7-week program was delivered in closed groups and comprised information modules, action-planning activities, moderated discussion boards, and weekly peer-facilitated 'live chats'. A randomised controlled trial was conducted to establish the effectiveness of the Positive Outlook program compared to a 'usual care' control. Participants were HIV-positive gay men 18 years or older living in Australia. Primary outcomes were evaluated at three time-points (baseline, post-intervention and 12-week's post-intervention follow-up) and included HIV-related quality of life (PROQOL-HIV), outcomes of health education (HeiQ) and HIV specific self-efficacy (Positive Outlook Self-Efficacy Scale). A total of 132 gay men with HIV in Australia were randomly allocated to the intervention (n = 68) or usual care control (n = 64) groups. Maximum likelihood marginal-linear modelling indicated significant improvement in the intervention group on the PROQOL-HIV subscales of body change ($p = 0.036$), social relationships ($p = 0.035$) and emotional distress ($p = 0.031$); the HeiQ subscales of health-directed activity ($p = 0.048$); constructive attitudes and approaches ($p = 0.015$); skill and technique acquisition ($p = 0.046$) and health service navigation ($p = 0.008$); and the Positive Outlook Self-Efficacy Scale on the subscales of relationships ($p = 0.019$); social participation ($p = 0.006$); and emotions ($p = 0.041$). Online delivery of self-management programs is feasible and has the potential to improve quality of life, self-

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management skills and domain specific self-efficacy for gay men with HIV.

Keywords HIV · Self-management · Quality of life · Randomised controlled trial · Positive Outlook Program · Internet · Online · Web-based

Introduction

The past 20 years has seen large improvements in life expectancy and reduced mortality rates for people with HIV (PWHIV). People newly diagnosed with HIV who have access to combination Antiretroviral Therapy (cART) regimens today have a life expectancy nearing that of their uninfected peers [1, 2], but psychosocial issues continue to have a prominent impact on the lives of individuals living with HIV [3–5]. Up to 40 % of PWHIV experience depression; a rate significantly higher than the general population [6, 7]. Disclosure of HIV status, and the management of HIV within intimate relationships are constant points of stress and uncertainty for PWHIV [8–10]. Disclosure of HIV status provides a means for social support and has found to be protective against depression and participation in high-risk sexual behaviours [9, 11]. Quality of life among PWHIV is significantly influenced by social support, coping style and depression [12–16]. However, health issues, secrecy, issues of disclosure, depression, and perhaps most importantly, stigma, present profound barriers to the maintenance of valued relationships and social support [10, 17].

Self-management programs have demonstrated effectiveness in a range of chronic conditions including diabetes [18], arthritis [19], cardiovascular conditions [20] and vision loss [21] and are recommended by the World Health Organization as a best practice in the clinical care of individuals with chronic conditions [22]. HIV-specific self-management interventions have been demonstrated to improve outcomes in PWHIV, including adherence to cART [23–25], symptom frequency and intensity [26–29], stress and anxiety management [29, 30], and mood and coping strategies [25, 31].

In recent years, the Internet has become a frequent source of health information [32]. The Internet is accessible 24 h a day and is relatively cheap to use. In 2010–2011, 79 % of households in Australia had home internet access and 83 % of households had access to a computer [33]. Online interventions are becoming increasingly employed for PWHIV [34], however, there is little empirical evidence of the effectiveness of such programs on the health and well-being of PWHIV. Barriers to traditional face-to-face programs include location, stigma, work hours and lack of association with community organisations delivering these programs [35, 36]. Online self-management interventions may offer several advantages for PWHIV [37–39], including time, convenience and anonymity [35], but the efficacy of online self-management programs for PWHIV has not been adequately explored.

The Positive Outlook Program was initiated to address existing limitations in current approaches to HIV management and enhance the self-management skills, self-efficacy, psychosocial status and overall quality of life of HIV positive gay men in Australia. This paper describes the primary outcomes of a randomised controlled trial (RCT) evaluating the effectiveness of the Positive Outlook Program.

Methods

The Positive Outlook study evaluated the effectiveness of an online self-management group intervention compared to usual care controls for gay men living with HIV. Details of the study protocol have been published elsewhere [40].

Recruitment

Between December 2012 and June 2013, HIV-positive gay men were recruited through advertisements on Facebook, community organisation websites, and in the gay press, AIDS council offices and primary care clinics. Men were eligible for participation if they self-identified as gay, homosexual or MSM (men who have sex with men); were 18 years or older and living in Australia; had adequate English to enable participation; and had access to a computer and the Internet. Potential participants registered their interest on the study website. The primary researcher then sent electronic information and consent forms. All study participants provided electronic consent. The study was approved by Monash University Human Research Ethics Committee; The Alfred Hospital, The AIDS Council of New South Wales and the Victorian AIDS Council.

Procedures

Baseline assessments and registration forms were completed electronically. Upon receipt of completed forms, participants were assigned a unique participant number, which was recorded in a secure electronic database.

Randomisation

A researcher who was not involved in the daily study operations allocated participants to the intervention or control group using a list of computer-generated random numbers. Once randomisation was completed, the primary researcher emailed each participant advising them of their group allocation.

Intervention

A multi-faceted needs assessment informed the development of the Positive Outlook intervention and identified the priority areas of the program as: (1) managing the emotional impact of HIV (2), disclosing HIV status to family and friends (3), maintaining social connectedness (4), managing HIV within intimate relationships, and (5) disclosure of HIV status to intimate partners [41].

Program design is described in-depth in the protocol paper [40]. Briefly, the program was based on self-efficacy theory, a key concept of Banduras' social learning theory [42], and utilised a self-management approach [43] to enhance participants' skills, confidence and abilities to manage the psychosocial aspects of HIV in their daily lives. Self-management focuses on the centrality of the person/patient in the management of their condition(s) and optimising quality of life. The intervention encouraged participants to take responsibility for managing the physical, social and emotional aspects of health and focused on behavioural changes. An overview of weekly modules and group discussion topics is presented in Table 1.

The program was delivered as closed groups with 15 participants per group. A peer support officer from a community organisation supporting PWHIV facilitated each group. Over 7 weeks, participants were encouraged to log onto the program for approximately 90 min per week. The program was accessible through a password protected website and consisted of a series of information modules, goal setting and action planning activities and discussion boards. Participants were also encouraged to attend a weekly live group chat session during which the facilitators led participants through guided 'discussions' in real time via a closed online forum. Discussions were scheduled on week nights and lasted 2 h. Participants and facilitators used pseudonyms and were anonymous to one another. Facilitators were responsible for modelling desirable participation; monitoring and facilitating the live chats and discussion boards; and providing additional information and feedback regarding goal setting and action planning activities. Participants received weekly reminders of the program via email and SMS from an external facilitator (the primary researcher).

Control

Control group participants continued with their 'usual care', including primary health and community based services and supports without any other additional intervention.

Primary Outcomes

The primary outcomes of this study were HIV-related quality of life; health education outcomes; and HIV-specific self-efficacy. These outcomes were measured at three time points: baseline; immediately post intervention (8-weeks post randomisation); and 12-weeks after completion of the program (referred here on as 12-week follow-up). Data was collected online (via Survey Monkey). Electronic questionnaires were emailed to participants by the primary researcher (TM) at the three time points. Participants were given two weeks to complete follow-up questionnaires and received email, SMS and phone reminders as required.

We have previously published detailed information about each of the outcome measures including descriptions of their psychometric properties [40]. In brief, health-related quality of life was assessed using validated domains (subscales) of the PROQOL-HIV. The PROQOL-HIV demonstrates good convergent and discriminant validity and reliability (Cronbach alphas 0.77–0.89) [44]. Subscales of the Health Education Impact Questionnaire (HeiQ) were used to evaluate the effectiveness of the program on improving patient education and self-management skills [45]. It has demonstrated high reliability with Cronbach alphas ranging from 0.70 to 0.83 for each of the dimensions [46].

Table 1 Program overview

	Topic	Chat topic
Week 1	Part 1: Orientation	Introductions and program expectations; health goals
	Part 2: Maintaining a healthy lifestyle	
Week 2	HIV and you: emotional well being and social connectedness	Stress management and depression
Week 3	Talking about HIV: disclosure of positive status to friends and family	Disclosure
Week 4	HIV, you and others: HIV and intimate relationships; safe sex basics	Relationships
Week 5	HIV, you and others: disclosure to partners	Disclosure to intimate partners
Week 6	HIV, you and others: managing risk	Risks within intimate relationships
Week 7	Wrapping up: review	Medications; program review; goodbye

When selecting outcome measures to evaluate interventions, a close match between the instruments used and the specific constructs the health program is attempting to influence is vital [47]. In situations where no existing instruments with established validity and reliability measure the constructs targeted in the intervention, use of a scale specifically designed for the intervention is appropriate [47]. The Positive Outlook Program specifically aimed to enhance HIV-specific self-efficacy, particularly surrounding disclosure and the negotiation of intimate relationships. No existing instruments examined these constructs. Therefore the positive outlook self-efficacy scale (POSE) was developed for this study. The scale is comprised of 19 questions, which are broken down into five individual dimensions including knowledge, communication, relationships, social participation and emotions. Each question is scored on a scale of one to ten.

Demographic information was collected for all participants. Secondary outcome measures were also collected at the three time-points and included social support (as measured by the Duke Social Support Index), health-related quality of life (as measured by the SF-12), general self-efficacy (as measured by the Generalised Self-Efficacy Scale), adjustment to HIV (as measured by the Adjustment to HIV Scale) and depression anxiety and stress (as measured by the Depression, Anxiety and Stress Scale) and will be reported separately.

Sample Size

A power calculation was undertaken based on findings from a study by Gifford et al., which used self-efficacy for controlling HIV symptoms as the primary outcome measure [48]. This study employed a symptom self-efficacy scale developed specifically for measuring the impact of self-management interventions for chronic diseases, and closely reflects the self-efficacy measure developed for use in evaluating the Positive Outlook program. Self-efficacy for controlling HIV symptoms increased in the intervention group, and decreased in the control group (mean difference $= 11$, $SD = 19.8$); $p = 0.02$) [48]. Based on these findings, a sample size of 52 in each group was estimated to be sufficient to identify a moderate to large effect size ($d = 0.5$–0.8) with 80 % power and 5 % significance. This sample size was inflated by 20 % to account for attrition. Therefore we aimed to recruit a total sample of 130.

Statistical Analysis

Contingency table analyses were undertaken to compare study participants baseline characteristics by study group. Maximum likelihood estimation using marginal linear modelling was undertaken on repeated measures data to compare the average marginal effect of the intervention across primary outcomes. It is well known that maximum likelihood estimation is robust to attrition in longitudinal models assuming attrition follows a missing at random (MAR) process (i.e. that response missingness at a particular time-point can be dependent on observed covariates and outcome responses prior) [49]. In these analyses, main effects for study group and time (discrete), and time by study group interaction terms were modelled as fixed effects. To account for observed heterogeneity of within-subject covariance and variance across study measurements, linear models were estimated using an unstructured within-subject residual covariance structure. Robust variance estimation [50] was specified in modelling and post hoc contrasts of simple effects providing correct standard errors in light of any model misspecification.

Model-based marginal mean estimations were produced, and joint and partial group by time interactions were examined using post-estimation Wald tests to explore the effect of the intervention over the study period. For each group by time interaction, an intervention effect was estimated using Cohen's d(d) [51] derived from marginal mean differences and pooled model based standard deviations (i.e. group by time standard errors and cell n's). Statistical significance was assessed at the 5 % level and for each outcome the group by time interaction was the focus of analysis—the study's a priori focus was estimation of a baseline to 12-week follow-up intervention effect, so baseline to 8-week and 8- to 12-week comparisons in the statistical analysis were considered exploratory and Bonferonni adjusted. Statistical analyses were conducted using Stata version 13 [52].

The priori analysis plan proposed an analysis of covariance (ANCOVA) approach to explore the differences in primary study outcomes across study groups at discrete study time points [40]. However, due to imbalance in participant observations and attrition, linear marginal modelling using maximum likelihood estimation was considered a more appropriate method in order to minimise bias and error in estimating the effect of the intervention.

Results

Participants

Of the 227 men who registered interest in the study, 132 (58 %) completed the registration form and baseline assessments and were randomised to the intervention (n = 68) or usual care control (n = 64) group. The trial arms were balanced at baseline with no statistically significant differences in observed participant characteristics (Table 2). During the course of the intervention, six

Table 2 Baseline sample characteristics by study group: counts (%) and probability values (p values) from Chi square inferential tests unless indicated otherwise

Socio-demographic characteristics	Intervention group	Control group	Total	*p* value
Age, years, mean (SD)	42.6 (10.5)	42.0 (10.5)	42.3 (10.4)	0.736[a]
Smoking status				0.955
Smoker	22 (32.2)	21 (32.8)	43 (32.6)	
Non-smoker	46 (67.7)	43 (67.2)	89 (67.4)	
Marital status				0.325
Single	48 (70.6)	40 (62.5)	88 (66.7)	
Partnered	20 (29.4)	24 (37.5)	44 (33.3)	
Education				0.681
Secondary school	18 (26.5)	19 (29.7)	37 (28.0)	
Tertiary qualification	50 (73.5)	45 (70.3)	95 (72.0)	
Employment status				0.478
Full time	43 (63.2)	34 (53.1)	77 (58.3)	
Part time	9 (13.2)	12 (18.7)	21 (15.9)	
Unemployed	16 (23.5)	18 (28.1)	34 (25.8)	
Income (weekly)				0.517
<$600	23 (33.8)	26 (40.6)	49 (37.1)	
$600–$999	22 (32.3)	22 (34.4)	44 (33.3)	
>$999	23 (33.8)	16 (25.0)	39 (29.5)	
Country of birth				0.127
Australia	45 (66.2)	50 (78.1)	95 (72.0)	
Other	23 (33.8)	14 (21.9)	37 (28.0)	
Living situation				0.719
Alone	27 (39.7)	24 (37.5)	51 (38.6)	
With partner	16 (23.5)	19 (29.7)	35 (26.5)	
With others	25 (36.8)	21 (32.8)	46 (34.8)	
Years diagnosed HIV+, median (IQR)	7 (17)	6 (13)	6 (14)	0.197[b]
Taking ARV?				0.697
Yes	20 (90.9)	15 (68.2)	35 (79.5)	
No	2 (9.1)	7 (31.8)	9 (20.4)	
Years taking ARV, median (IQR)	4 (14)	4 (6)	4 (12)	0.191[b]

[a] Independent samples t-test

[b] Mann–Whitney *U* test

participants formally withdrew, citing time constraints as their reason for withdrawal. Participant disposition is given in Fig. 1.

Outcomes

Table 3 shows the results from linear marginal models for each of the primary outcomes.

PROQOL-HIV

There was significant improvement by the intervention group on the PROQOL-HIV subscales of body change (Wald $\chi^2(2) = 6.63$, $p = 0.036$), social relationships (Wald $\chi^2(2) = 6.71$, $p = 0.035$) and emotional distress (Wald $\chi^2(2) = 6.93$, $p = 0.031$). Tests of the partial interactions indicated that for body change, intervention group participants demonstrated a greater improvement in scores between baseline and 12-week follow-up than control participants (intervention means: 61.8 vs. 70.8; control means: 69.3 vs. 68.2, Wald $\chi^2(1) = 5.43$, $p = 0.020$). There was a similar difference in improvement in body change scores between baseline and the 8-week follow-up (Table 3), but this difference did not reach statistical significance (Wald $\chi^2(1) = 4.03$, $p = 0.089$). For social relationships, the intervention group demonstrated significant improvements between baseline and 12-week follow-up from 69.3 to 78.2, while the control group declined from 74.4 to 73.7 (Wald $\chi^2(1) = 3.92$, $p = 0.047$). In terms of emotional distress, participants receiving the intervention showed greater improvement between baseline and the 8-week follow-up compared with controls (intervention means: 61.0 vs. 67.0; control means: 66.0 vs. 61.9, Wald

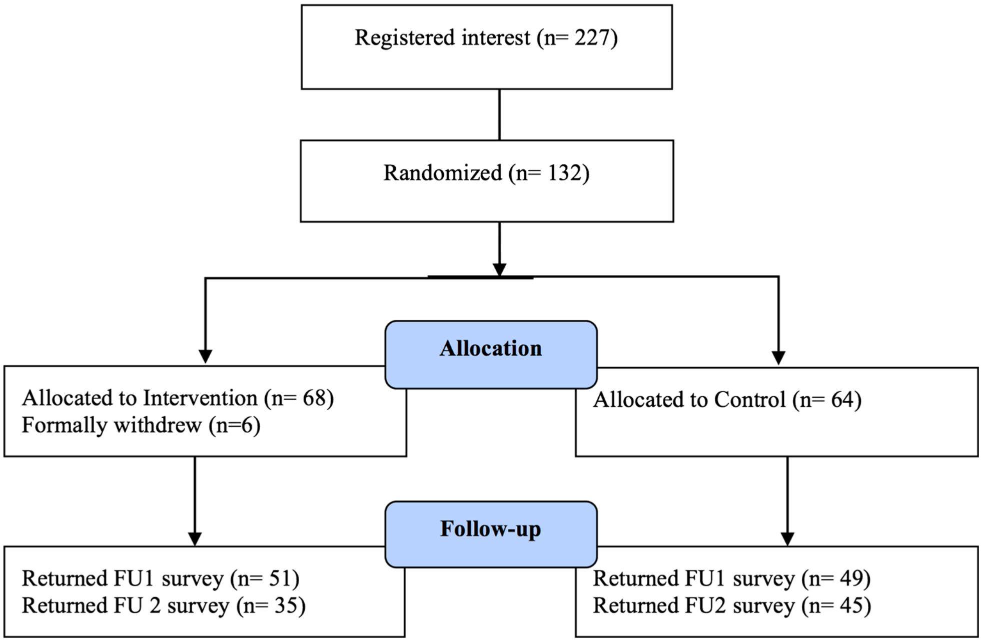

Fig. 1 Flow of participants through trial

$\chi^2(1) = 6.90$, $p = 0.017$), but no significant difference in emotional distress was observed between baseline and 12-week follow-up (Wald $\chi^2(1) = 1.9$, $p = 0.169$).

HEIQ

Significant improvements by the intervention group compared with control participants were observed on the HeiQ subscales of health directed activity (Wald $\chi^2(2) = 6.06$, $p = 0.048$); constructive attitudes and approaches (Wald $\chi^2(2) = 8.35$, $p = 0.015$); skill and technique acquisition (Wald $\chi^2(2) = 6.18$, $p = 0.046$) and health service navigation (Wald $\chi^2(2) = 9.47$, $p = 0.008$).

Tests of partial interaction showed that intervention group participants demonstrated significant improvement in health directed activity between baseline and study end (12-weeks post-intervention) from 2.9 to 3.0, while control participants experienced a decline over the same period (control mean 3.0–2.8, Wald $\chi^2(1) = 6.052$, $p = 0.014$). For the subscale of constructive attitudes and approaches, intervention participants again improved significantly while control participants experienced decline between baseline and 8-week follow-up (intervention means: 2.9–3.0 vs. control means: 3.1–2.9, Wald $\chi^2(1) = 6.13$, $p = 0.026$). However, there were no significant differences across study groups between baseline and 12-week follow-up (Wald $\chi^2(1) = 0.10$, $p = 0.757$). The intervention group significantly improved their skill and technique acquisition scores when compared with control group between baseline and 8-weeks (intervention means: 2.8 to 2.9 vs. control means: 2.8–2.8, Wald $\chi^2(1) = 5.22$, $p = 0.044$). Again, no significant differences were detected across study groups between baseline and 12-week follow-up (Wald $\chi^2(1) = 0.04$, $p = 0.834$). Health service navigation significantly improved for the intervention group between baseline and post-intervention (8-weeks) (intervention means: 3.1–3.3 vs. control means: 3.2–3.1; Wald $\chi^2(1) = 6.78, p = 0.018$). This improvement, however, was inconsistent and confined to the first follow-up with control participants showing improved health service navigation between 8- and 12-weeks follow-ups (control 3.1–3.2 vs. intervention means: 3.3–3.2, Wald $\chi^2(1) = 5.42$, $p = 0.040$).

POSE

Significant improvements by the intervention group compared with control group participants were observed on the POSE when compared with control participants for the subscales of relationships (Wald $\chi^2(2) = 7.87$ $p = 0.019$); social participation (Wald $\chi^2(2) = 10.20$, $p = 0.006$); and emotions (Wald $\chi^2(2) = 6.40$, $p = 0.041$).

Based on tests of partial interaction, intervention participants demonstrated significantly greater improvements in relationships between baseline and 8-week follow-up compared with control (intervention means: 5.0–6.0 vs. control means: 5.2–5.4, Wald $\chi^2(1) = 7.87$, $p = 0.010$). However there was no significant difference in relationship

Table 3 Primary outcomes at baseline, 8 week and 12 week follow-up by study group: marginal means, standard error (SE), effect size and probability values (p values) for group by time interactions from linear marginal models

	Group by time interaction: *p* value[a]	Intervention group: marginal mean (SE)[a]			Control group: marginal mean (SE)			Partial group by time contrasts: effect size[b] (*p* value[a]^)		
		Baseline	8 weeks	12 week	Baseline	8 weeks	12 week	Baseline vs 8 weeks	8 weeks vs 12 week	Baseline vs 12 week
PROQOL-HIV (0–100)										
PHS	0.062	62.5 (2.70)	66.2 (3.26)	58.6 (3.26)	67.5 (3.00)	65.6 (3.72)	67.5 (3.26)	0.24 (0.238)	0.42 (0.037)	0.18 (0.230)
BC	0.036	61.8 (3.43)	68.9 (3.16)	70.8 (3.20)	69.3 (3.77)	67.5 (4.34)	68.2 (3.59)	0.33 (0.089)	0.05 (>0.999)	0.41 (0.020)
SR	0.035	69.3 (3.70)	73.4 (4.00)	78.2 (3.41)	74.4 (3.51)	69.1 (4.25)	73.7 (3.77)	0.32 (0.051)	0.01 (>0.999)	0.37 (0.047)
IR	0.154	47.5 (3.67)	53.9 (4.14)	57.3 (4.14)	48.9 (4.33)	48.2 (4.66)	50.5 (4.45)	0.22 (0.243)	0.04 (>0.999)	0.28 (0.097)
ST	0.327	48.4 (4.19)	55.8 (4.13)	57.5 (4.55)	55.2 (4.32)	56.3 (4.32)	58.4 (4.25)	0.20 (0.301)	0.02 (>0.999)	0.19 (0.264)
ED	0.031	61.0 (3.91)	67.0 (3.75)	64.5 (4.03)	66.0 (3.21)	61.9 (3.93)	63.8 (3.50)	0.39 (0.017)	0.17 (0.607)	0.24 (0.269)
HC	0.084	55.7 (3.31)	64.4 (3.31)	64.5 (3.23)	55.6 (3.58)	56.2 (3.69)	61.4 (3.37)	0.32 (0.052)	0.23 (0.468)	0.13 (0.431)
TI	0.159	80.9 (2.19)	76.7 (2.01)	76.9 (2.37)	79.2 (2.61)	72.2 (2.69)	69.3 (3.25)	0.18 (0.351)	0.20 (0.737)	0.35 (0.085)
HeiQ (0–4)										
HDA	0.048	2.9 (0.09)	2.9 (0.08)	3.0 (0.09)	3.0 (0.08)	2.9 (0.10)	2.8 (0.10)	0.22 (0.289)	0.27 (0.222)	0.49 (0.014)
PAE	0.458	3.1 (0.05)	3.0 (0.06)	3.0 (0.06)	3.1 (0.07)	2.9 (0.08)	2.8 (0.08)	0.14 (0.776)	0.10 (>0.999)	0.24 (0.232)
ED	0.103	3.5 (0.10)	3.8 (0.09)	3.8 (0.10)	3.6 (0.09)	3.7 (0.10)	3.7 (0.09)	0.25 (0.148)	0.06 (>0.999)	0.32 (0.063)
SMI	0.556	3.1 (0.05)	3.1 (0.04)	3.1 (0.05)	3.2 (0.05)	3.1 (0.05)	3.1 (0.05)	0.19 (0.591)	0.03 (>0.999)	0.16 (0.406)
CAA	0.015	2.9 (0.07)	3.0 (0.06)	3.0 (0.08)	3.1 (0.07)	2.9 (0.07)	3.0 (0.08)	0.44 (0.026)	0.39 (0.057)	0.06 (0.757)
STA	0.046	2.8 (0.06)	2.9 (0.04)	2.9 (0.07)	2.8 (0.05)	2.8 (0.06)	2.9 (0.06)	0.39 (0.044)	0.38 (0.161)	0.04 (0.834)
SIS	0.246	2.5 (0.09)	2.6 (0.07)	2.6 (0.10)	2.5 (0.07)	2.6 (0.08)	2.6 (0.08)	0.21 (0.300)	0.01 (>0.999)	0.21 (0.194)
HSN	0.008	3.1 (0.07)	3.3 (0.07)	3.2 (0.08)	3.2 (0.06)	3.1 (0.05)	3.2 (0.06)	0.39 (0.018)	0.41 (0.040)	0.02 (0.915)
POSE (0-10)										
Knowledge	0.898	8.0 (0.25)	8.2 (0.25)	8.1 (0.27)	7.9 (0.33)	8.1(0.30)	8.0 (0.30)	0.0 (>0.999)	0.07 (>0.999)	0.07 (0.694)
Communication	0.064	5.2 (0.34)	6.0 (0.32)	5.9 (0.40)	5.1 (0.29)	5.3 (0.34)	5.6 (0.33)	0.27 (0.047)	0.2 (0.345)	0.08 (0.566)
Relationships	0.019	5.0 (0.25)	6.0 (0.29)	5.8 (0.29)	5.2 (0.30)	5.4 (0.30)	5.5 (0.30)	0.38 (0.010)	0.18 (0.467)	0.23 (0.126)
Social Participation	0.006	4.9 (0.29)	5.7 (0.26)	5.3 (0.33)	5.3 (0.32)	5.0 (0.32)	5.4 (0.37)	0.45 (0.004)	0.33 (0.119)	0.13 (0.432)
Emotions	0.041	5.2 (0.25)	5.9 (0.25)	5.7 (0.33)	5.6 (0.32)	5.5 (0.32)	5.8 (0.32)	0.33 (0.049)	0.28 (0.180)	0.06 (0.731)

Unstructured residual covariance matrix specified in modelling

PHS physical health and symptoms; BC body change; SR social relationships; IR intimate relationships; ST stigma; ED emotional distress; HC health concerns; TI treatment impact; HDA health directed activity; PAE positive and active engagement in life; ED emotional distress; SM self monitoring and insight; CAA constructive attitudes and approaches; STA skill and technique acquisition; SIS social integration and support; HSN health service navigation

^ *p* values are Bonferonni adjusted for baseline >8 weeks and 8 weeks >12 weeks comparisons ($p_i^b = kp_i$, where p_i^b is the Bonferonni corrected p value and k is the number of comparisons undertaken)

[a] Robust standard errors specified in modelling

[b] Cohen's d

self-efficacy across study groups between baseline and 12-week follow-up (Wald $\chi^2(1) = 2.3$, $p = 0.126$). Social participation significantly improved for the intervention group between baseline and post-intervention (8-weeks) 4.9–5.7, while control group participants demonstrated a decline from 5.3–5.0 (Wald $\chi^2(1) = 9.60$, $p = 0.004$). Again, there was no significant difference in social participation across study groups between baseline and study end (12-weeks post-intervention) (Wald $\chi^2(1) = 0.62$, $p = 0.432$). Intervention group scores for emotions also improved between baseline and 8-weeks from 5.2 to 5.9, while the control group declined from 5.6 to 5.5 (Wald $\chi^2(1) = 5.05$, $p = 0.049$). No significant differences between study groups were detected however between baseline and study end (Wald $\chi^2(1) = 0.12$, $p = 0.731$).

Discussion

This randomised study found evidence that an online group-based self-management program led to significant improvements in quality of life, self-management skills and HIV-specific self-efficacy for gay men with HIV. A key focus of our intervention was the psychosocial issues affecting gay men's daily life. Consistent improvements in psychosocial domains associated with emotional distress and social relationships/participation after the Positive Outlook intervention were found. These findings are consistent with recent research showing that online self-management interventions are effective at improving physical, emotional and social outcomes for people with chronic conditions [19, 39, 53–55].

In the present study, the greatest degree of change reported by the intervention group was on HIV-specific self-efficacy as measured by the POSE scale. This is consistent with a true effect of the intervention given the program design was based on self-efficacy theory. Further, it adds support to research indicating an association between theory-based online interventions and larger effect sizes [56]. Intervention group participants demonstrated mean improvements on each of the POSE subscales, reaching the level of significance for 'relationships', 'social participation' and 'emotions' between baseline and 8-week follow-up. While 'knowledge' scores improved for both groups, baseline scores were high and improvement was only slight. A slight decline was observed between 8- and 12-weeks follow-up on all subscales of the POSE scale, however 12-week follow-up scores remained above baseline for every subscale. The self-management approach and group setting of the Positive Outlook program provided numerous opportunities to improve self-efficacy. Participants were able to learn from one another, model desirable behaviour, and provide each other with support and encouragement. They were able to share their experiences and problem-solve issues together. These effects are consistent with improvement in disease-specific self-efficacy observed in other studies of self-management interventions [21, 39, 57] and online interventions [58] for people with chronic conditions.

Participants obtained social support by participating in the group, interacting with peers via the discussion boards and during the live chat. Significant improvements were observed in the PROQOL-HIV and POSE subscales concerned with social relationships/participation and emotions/emotional distress and non-significant improvements were demonstrated by intervention participants over the period of the study on the HeiQ subscales 'emotional distress' and 'social integration and support' and PROQOL-HIV subscales 'intimate relationships' and 'stigma.' These findings are consistent with the focus of the intervention on these constructs, previous research demonstrating the clear link between higher levels of perceived social support and reduced psychological distress [59, 60] and similar improvements in emotional distress and social support reported in studies evaluating online self-management for people with neurological conditions and type 2 diabetes [53, 55].

Significant improvement in HeiQ subscales 'constructive attitudes and approaches' and 'skill and technique acquisition' may be attributed to the focus of the intervention on developing skills for disclosure, risk reduction and dealing with negative reactions. In accordance with self-management and self-efficacy theory, the positive outlook program incorporated a number of strategies to encourage behaviour change including problem solving, communication skills development, barrier identification, behaviour monitoring, goal setting and action planning. The improvements seen in these domains support research indicating that online interventions which incorporate more behaviour change techniques tend to produce larger effect sizes than those utilising fewer techniques [56].

The Positive Outlook Program was less focussed on the physical and medical aspects of living with HIV, as reflected in the lack of improvements by the intervention group on the PROQOL-HIV subscales of 'physical health and symptoms', 'health concerns' and 'treatment impact', and the HeiQ subscale 'physical activity and exercise'. Participants were encouraged to make health related goals and to report their progress via discussion boards and during live chats. This may explain the significant improvements by the intervention group in the HeiQ subscale 'health-directed activity', however it may have also reflected the decline in scores by the control group. The significant improvement in the subscale of 'body change' was unexpected. Discussions during the live chats briefly included some discussion of body image and acceptance, which may have had a positive impact on this outcome for some participants.

Overall, the majority of improvements obtained through participating in the Positive Outlook intervention were detected between baseline and 8-week follow-up. While the intervention group participants demonstrated improved HIV-specific self-efficacy across a number of the POSE domains, none of the subscales remained significant at 12-week follow-up. This pattern of a diminishing effect was also observed with some of the other domains, including the PROQOL-HIV subscale 'emotional distress', and the HeiQ subscales 'constructive attitudes and approaches', 'skill and technique acquisition' and 'health service navigation'. These findings suggest that the positive effects of the program wane over time once participants are no longer participating in program activities.

The diminishing intervention effect may in part be due to the level of program engagement observed in our study. Although process analysis has not yet been conducted, program facilitators and the intervention team noted that participants use of the discussion boards and the 'live chats' waned over time and were not sustained at the level proposed in the study protocol. A more intensive and longer intervention program with the aim of achieving and maintaining higher levels of participant engagement may lead to better, more sustainable outcomes [61]. Email and SMS were used for this study, but only as reminders and prompts for participation and came from the primary researcher rather than the group facilitators in order to maintain participants' anonymity. The use of these forms of interaction have been found to be associated with increased effect sizes [56] and may be an opportunity to maintain engagement and intervention effect. Previous studies have found that online programs where participants receive individual communications with a human facilitator demonstrate more robust outcomes than programs that do not offer this addition [62–64]. In our study participants had the option to communicate directly and privately via the online platform with the group facilitators, but this function was not widely used. Promotion of this opportunity for interaction may be another opportunity to achieve and sustain an intervention effect and promote higher retention rates.

The diminished effect may also be attributable to the duration of the program and the lack of opportunities for ongoing interaction and engagement. Further research is required to establish if participation in the Positive Outlook Program, or a modified version with some opportunities for participants to continue interactions over a longer period of time, can produce a clear and sustained effect on primary outcomes at six and 12-month follow-up. We hypothesise that at the cessation of the current program, a stepped reduction in facilitation and active efforts to link participants into ongoing supports may have a more sustained impact on social isolation (and associated emotional distress), and may increase the sustainability of the effect of the intervention and promote higher retention rates.

Several limitations to the current study should be considered. The use of the newly developed POSE scale may been seen as a limitation. Although validity and reliability of this scale has not yet been established, the lack of a validated alternative scale meant the POSE scale was able to be designed to match the causal pathways of the intervention and was therefore the most appropriate way to measure the effect of the intervention on the priority outcomes identified in the needs assessment. The fact that the scale behaved in a similar fashion to the standardised measures lends robustness to the results from this scale. Future work will focus on establishing the validity and reliability of the scale.

Data regarding number of logins, modules completed and post readings would have been beneficial in determining attenuation, however, the software did not enable this function. Rates of attrition were relatively high, although this is a consistent feature of web-based research [65] and the modelling approach adopted (more specifically, maximum likelihood estimation using an unstructured within-subject covariance structure) provides unbiased estimates assuming the data were MAR. It also should be noted the large number of outcome measures used in the study increased risk of type I error in analyses. However, the improvements in psychosocial dimensions were greater amongst intervention participants, consistent across measured outcomes and greater in domains targeted by the intervention lends robustness to the study results. Self-selection bias where frequent computer users may be more likely to participate [66] is a common concern in online behavioural interventions and may have been present here. Similarly, it was not possible to blind participants to the intervention and thus attention effect cannot be ruled out. Finally, repeat assessments at six and 12 months were beyond the scope of this study, but should be considered in the future to determine the long-term effects of the intervention.

Future studies of online self-management programs for people with HIV should focus on identifying the factors that mediate success and defining the population for whom such interventions are most effective. For example, it will be important to extend the findings of this study and assess the feasibility and effectiveness of online self-management for different populations living with HIV including women, heterosexual men and people from culturally and linguistically diverse backgrounds.

Substantial evidence demonstrates the pervasive impact stigma, limited HIV disclosure and social isolation have on the quality of life and well-being of PWHIV despite longstanding community-based face to face programs. It is critical that innovative programs are developed that enable people with HIV to address these ubiquitous issues. We conducted the first study of an online group self-management program for gay men with HIV specifically targeting psychosocial issues, and the first online self-management program for this population to be evaluated in a randomised trial. Using online delivery we were able to overcome many of the barriers commonly experienced by individuals with HIV accessing health programs including transportation, lack of availability during normal working hours, weak identification with community organisations and the desire for anonymity. In conclusion, this study demonstrated the efficacy of online self-management in building the confidence and skills of gay men with HIV to manage psychosocial issues associated with HIV and highlights the advantages of delivering online programs for this population, including the ability to facilitate participant engagement while maintaining anonymity.

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Authors' contributions TM, PA, KM, SS, SG and JE contributed to the design of the study. PA helped conceive the idea for the analysis of the trial, devised a statistical plan and formulated statistical code for the analysis. TM drafted the manuscript. TM, PA, KM, SS, SG and JE assisted with interpreting the results and reviewed the manuscript. The manuscript has been read and approved by all authors.

Compliance with Ethical Standards

Competing interests The authors have no competing interests to declare.

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