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Facilitating mental health help-seeking by youth with a dedicated online program: a Phase II randomised controlled trial of *Link*

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ABSTRACT

Objective: A pilot study exploring the feasibility of a dedicated online youth mental health help-seeking intervention and study design in order to identify any modifications needed before commencement of the Phase III randomised controlled trial (RCT).

Design: A Phase II RCT with 1:1 randomisation to either the intervention or control arm.

Setting: An online study conducted Australia-wide.

Participants: 51 young people aged 18–25 living in Australia were recruited via social media.

Intervention: *Link* is a dedicated online mental health help-seeking navigation tool that matches mental health issues, severity and preferences with appropriate youth-friendly online, phone and face-to-face services. The comparison group was usual help-seeking strategies with a link to google.com.

Main outcome measures: The primary outcome was the number of acceptability and feasibility criteria successfully met. Nine criteria assessed the acceptability and feasibility of the intervention and study design. Secondary outcomes, via online surveys (at baseline, 1 week and 1 month) measured service use, help-seeking intentions, psychological distress, barriers to help seeking, attitudes towards mental health help-seeking, mental health literacy, satisfaction and trust.

Results: 51 participants were randomised (intervention n=24; control n=27). Three out of four of the intervention and three out of five of the study design criteria were met. Unmet criteria could be addressed by modifications to the study design. Qualitative analysis demonstrated that *Link* was useful to participants and may have increased their positive experiences towards help-seeking. There were no observable differences between groups in any outcome measures and no harms detected.

Conclusion: Generally, *Link* and the study design were acceptable and feasible with modifications suggested for the three out of nine unmet criteria. As a result, the main trial will have shorter surveys and a simpler recruitment process, use positive affect as the primary outcome and no link to Google.com for the control arm.

Strengths and limitations of this study:

- A Phase II randomised controlled trial was conducted to assess the
 acceptability and feasibility of the intervention and the study design in
 preparation for the Phase III randomised controlled trial.
- An Australian wide study involving 18-24 year olds recruited online via social media.

- The intervention is based on the Theory of Planned Behaviour and designed to reduce barriers to help-seeking, and, increase help-seeking intentions and behaviours.
- Participatory design was used tailor the program for use with young adults.



INTRODUCTION

Mental health disorders account for the highest burden of disease in adolescence and young adulthood.[1] Up to one quarter of young people experience mental health problems with substantial negative effects on interpersonal relationships, functioning at school and work, general health and wellbeing.[2] Whilst there has been significant investment in mental health service promotion and delivery over the last decade,[3] only 35% of young people experiencing mental health problems seek professional help. [4,5]

The major barriers preventing young people from seeking help including lack of recognition of mental health problems,[6] lack of awareness about appropriate mental health services,[7,8] not being ready to seek help,[2] lack of clinical detection,[9] and the stigma associated with mental illness and seeking professional help.[10]

Facilitated access to treatment services is necessary to improve mental health outcomes,[11] particularly interventions aimed at increasing young people's willingness or readiness to seek help.[12] The international Delphi panel on mental disorders suggested technological solutions may improve treatments, access to care, and advance prevention and early intervention strategies.[13] Young people regularly use find information and access mental health services on the internet, and often prefer anonymous sources of help to traditional services.[14–16] However, help-seeking outcomes associated with existing websites and online interventions are rarely evaluated.[17,18]

The development of *Link* was based on the Medical Research Council guidelines for complex interventions as part of a comprehensive research program.[19,20] We set out to develop and evaluate *Link*, a dedicated online program to facilitate mental health help-seeking for young adults aged 18 to 25 years of age. First, a Preclinical Phase examined several theories of help-seeking and behaviour change to determine a suitable theoretical framework for *Link* with the Theory of Planned Behaviour selected.[21] Second, a Phase I study using an iterative participatory design process tailored the program for use with young adults.[22] This Phase II trial is the third in the series with the following objectives: (i) assess the acceptability and feasibility of the online intervention, *Link*, to guide young people to appropriate mental health care

or information; (ii) assess the acceptability and feasibility of the study design; and (iii) identify any modifications needed to the intervention or the study design before proceeding to the main trial. This study is limited as it was not powered to assess statistical significance and as such the results are descriptive, not generalisable, and should be interpreted with caution.

METHODS

Study Design

A two-arm randomised controlled trial was used with individuals randomised into balanced (1:1) parallel groups; either the intervention group (*Link*) or the control group ('usual search strategies'). Online recruitment and online surveys were used. This study is reported following the CONSORT guidelines.[23]

Participants

Recruitment

Two methods were trialled using various social media and online platforms such as GoogleAds, Facebook advertising and Gumtree: (1) a static advertising campaign with eight advertisements coupled with keywords; and (2) a dynamic advertising campaign, where advertisements regularly modified to maintain a high profile and visibility on the various platforms. Advertisements were limited to those living in Australia (for all platforms) and aged between 18 and 24 years (only Facebook allowed specification of age).

Sample Size

Consistent with Phase II studies, no power analyses were conducted as this study was not intended to assess statistical significance. We anticipated that a total sample size of 120 participants (60 in each arm) would be sufficient to test acceptability and feasibility, allowing for approximately 50% attrition, as is common in online recruitment strategies,[24], to ultimately reach a sample of 60 (30 in each arm) at the one-week timepoint.

Inclusion Criteria

The inclusion criteria comprised: (1) 18 to 25 years of age; (2) living in Australia; (3)

three contact details such as a current valid email address and residential address and either a phone number or alternative email address; and (4) sufficient English to complete the surveys and intervention.

Randomisation

The online survey service, QuON,[25] provided a secure server for collecting data with responses de-identified and stored securely at the University of Newcastle, Australia. An independent academic oversaw the randomisation process including generating the sequence for the random allocation using a random seed generator within QuON in random blocks of four, six or eight. Participants were randomly allocated to a trial arm after baseline and identified by a randomly allocated identification number. The researchers were blind to the randomisation sequence until data analysis had been carried out. Participants were emailed a link to either google.com (control) or *Link* (intervention) and therefore it was not feasible to blind participants.

Interventions

Control Arm: Usual help-seeking strategies

Participants allocated to the control arm received the following instructions: "Please search for information and help for an issue you are currently facing using whatever strategies you would normally use whether it's online or offline. The below link will direct you to www.google.com to begin your search".

The *Link* Intervention Arm

Participants allocated to the intervention arm were asked to seek help using *Link*, comprising three steps in a self-directed triage process: (i) *issues* (depression/anxiety, body image, drugs/alcohol, self-harm, suicide, bullying, and relationship problems), (ii) the Link *severity scale* (setting a level on an interactive pictorial sliding scale on a five-point scale to indicate level of severity from 'I'm OK', 'It's no big deal', 'It's a lot to handle', 'It's really tough' and 'It's a huge deal'), and; (iii) *service preference* (face-to-face, phone helpline, online chat or email therapy, or online information).

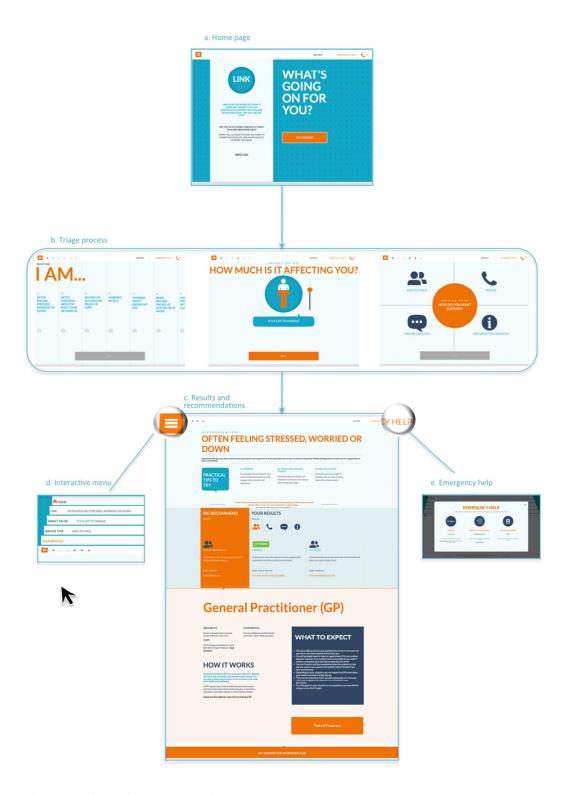


Figure 1. The webpages of *Link*

Three services appropriate to these specified needs and preferences were then presented with the following information: a description of the service; what to expect, costs and a link for direct access to the service. A 'recommended' service, in addition to the participants' preferred service type was also displayed, based on clinical need. For example, a participant selecting suicidal thoughts as an issue with a preference for online help would also be recommended a 24-hour crisis telephone service ('Lifeline') in addition to their preferred service type. There were 31 youth-friendly services included in the *Link* directory. The program took a minimum of 30 seconds to complete (in order to reduce attrition during the program), but participants could spend longer exploring their issues or return at a later time to where they had ended a previous session if they wished. Intervention participants had access to *Link* for the duration of the trial (one month in total). For the purposes of this study, participants accessed *Link* using their logon details to link their data with survey data. The development and prototype of the intervention is further described in another publication [21].

Measures

Primary outcome

Based on previously used criteria,[26] acceptability and feasibility of the intervention and study design are outlined in Table 1; four criteria assess the intervention and five criteria assess the study design. Based on the number of criteria met, the study design or intervention would be deemed 'not feasible' if no criteria were met, 'feasible with modifications' if some of the criteria were met, provided that modifications were possible, and 'feasible with no changes' if all the criteria were met.

Secondary outcomes

Help-seeking behaviours were assessed using the Mental Health Care Resource Use Questionnaire; [27] help-seeking intentions with the Stages of Change Questionnaire (range=1-4), with higher values indicating higher levels; [28] the General Help Seeking Questionnaire (range 1-7), with higher values indicating increased likelihood of seeking help; [29] and two items created ('I want to seek help for my problems' and 'I intend to seek help for my problems)' using the Research-Based Education and Quality Improvement guidelines (range=1-7), with higher values indicating a higher level of intention. [30] We assessed mental health with the Kessler Psychological Distress Scale (K10) (range=5-50), with higher values indicating higher psychological distress; [31] barriers to help-seeking with the Barriers to Adolescents Seeking Help scale (range=11-66), with higher scores indicating more barriers; [7,32] quality of life with the Adolescent Quality of Life Scale; [33] mental health help-seeking perceptions with four created items (Appendix A, Figure A1) ranging from 4-28, with higher scores indicating positive perceptions; and mental health literacy using the Mental Health Literacy Vignette. [34]

Further assessments at the one-week and one-month surveys included: Satisfaction and trust in the service and the likelihood of using the service again using the Client Satisfaction Questionnaire (range=8-40), with higher scores indicating higher satisfaction;[35] whether expectations were met using ten items adapted from Retolaza and Grandes (Appendix A, Figure A2) ranging from 10-50, with higher scores indicating more expectations met;[36] and general feedback with four openended questions (What did you most like/dislike about the program? Do you have any suggestions for improvements? General comments.)

Baseline, one-week post-intervention and one-month follow-up surveys were administered online. The baseline included all measures except for the questions about satisfaction and trust. The one-week survey included only the questions about satisfaction and trust. The one-month survey included all measures except measures of mental health literacy and perceptions.

Data Management and analysis

Data were collected using online surveys using QuON and data from *Link* (for intervention participants only). Participants logged onto the online survey using a secure username and password.

The Stata statistical package Version 13 was used for data analysis.[37] The primary outcome was the number of acceptability and feasibility items that were met. Descriptive statistics were used to describe the secondary outcomes. Effect sizes (Cohen's d) were calculated using bootstrapped standard deviations for the satisfaction and trust questions. For all other continuous outcomes, multiple regression analyses were performed in order to calculate post-estimation effect sizes; however, these are not reported due to the small sample size.

RESULTS

Study procedure

Figure 2 illustrates the participant flow throughout the study. The static advertising campaign ran from the 7th May to 12th June 2014 with a total of 23 participants randomised during these five weeks. Next, the dynamic campaign was used from 13th June to 19th August 2014 with a total of 28 participants randomised within this eleven-week period. The majority of participants (45, 88%) were recruited via Facebook advertising.

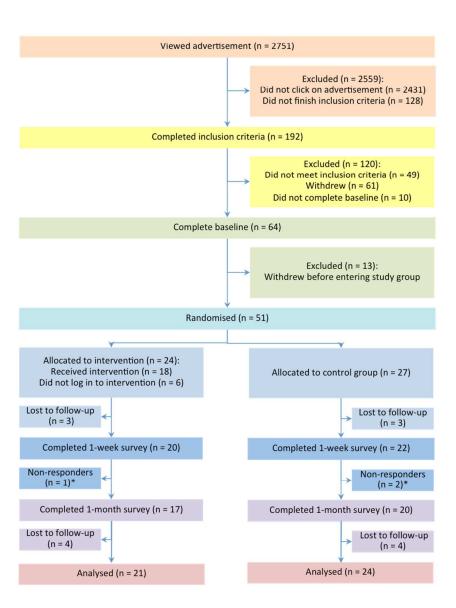


Figure 2. The study flow diagram.

* These participants did not complete the one week survey but completed the one month survey. *Note*: Withdrew before entering study group = Started baseline then withdrew, or completed baseline and withdrew before randomisation.

Of the 24 participants allocated to the intervention group, 18 (75%) accessed *Link*. Only two participants (11.8%) who completed the one-month follow-up assessment did not access *Link*.

Retention and assessment procedures

Retention and assessment procedures

Once participants were randomised into the study, attrition rates reduced. From the 51 randomised, only six participants (11.8%; three from each arm) were not included in the data analysis. A further three (5.9%) did not complete the one-week survey and six (11.8%) did not complete the one-month survey, leaving a total of 34 (66.7%) participants with complete data.



Table 1. Acceptability and feasbility criteria, outcomes and contingency plans

Questions	Criteria	Met?	Outcomes and contingency plan
Acceptability and feasibility of the inter	rvention		
Will intervention participants complete Link at least once?	85% of participants log on at least once	No	18/24 (75%) accessed the intervention. However, 15/17 (88%) of those completing the 1-month assessment accessed the intervention. As well as emailing allocation, all participants will receive their allocation online so they can immediately log onto google.com or Link without checking their email account. Improve the visibility of the link to the intervention in the emails with reminders containing the link.
Will there be any cross-contamination between arms?	No control participants use the intervention	Yes	0/27 control participants logged on to the intervention
Did the intervention cause harm?	No serious negative reports or feedback	Yes	There were no negative reports
Is the severity rating on the intervention useful? Acceptability and feasibility of study de	The severity rating correlates with level of distress (k10) by at least .6 esign and procedures	Yes	The correlation between severity and k10 = .69
Can we recruit quickly enough using social media?	200 eligible participants reached within three months	No	320/2751 (7%) who saw the advertisement completed the inclusion criteria. 49/192 (26%) who did complete the criteria were ineligible, leaving a total of 143 young adults recruited in a 15-week period, three weeks longer than anticipated. 1. New advertising campaign will be implemented including electronic direct mail, outsourced to a professional marketing manager, with weekly monitoring to adjust the language used in the ads and the keywords depending on the searches and interests of young people, other organisations using the keywords and the costs associated with the keywords. 2. Reduce the burden of participation by re-designing the sign-up process and shortening the surveys. 3. A new incentive scheme involving increasing the amount awarded to participants based on the number of surveys completed will also be used.
Were the measures in the survey useful?	All measures produce a meaningful and unique score	No	Some of the measures were difficult to interpret and use in analyses including the mental health literacy measure and the perceptions of mental health items. The length of the survey possibly contributed to attrition rates. The mental health literacy and perceptions of mental health items items will not be included in the main trial. An additional measure of positive and negative affect will be used as a primary outcome for the main trial. The control condition will not include a link to Google.com.
Do most eligible participants enrol into study?	80% of eligible participants complete the baseline and randomisation process	Yes	13/60 (20.3%) dropped out before completing the randomisation process. To further increase completion rates, surveys will be shorter.

Did the randomisation process work?	Equal numbers of participants in each group (within 10%) with similar demographics	Yes	27/51 (52.9%) were allocated to the control group and 24/51 (47.1%) were allocated to the <i>Link</i> intervention group.
Was the loss to follow-up reasonable?	At least half of the participants completing all surveys	Yes	34/51 (67%) completed all surveys. To further increase completion rates, surveys will be shorter



Baseline data

The mean age of participants was 20.9 years (Intervention: M=20.9, SD=2.1; Control: M=21.0, SD=1.9). Other baseline characteristics are listed in Table 2 by arm. There were no differences between groups using chi-squared (χ^2) and independent samples t-test statistics.

Table 2. Baseline characteristics by arm

	Control	Link	Total
	(N = 27)	(N = 24)	(N = 51)
	n(%)	n(%)	n(%)
Female	22(81.5)	17(70.8)	39(76.5)
Rural	9(3.3)	4(16.7)	13(25.5)
State			
Australian Capital Territory	4(14.8)	1(4.2)	5(9.8)
New South Wales	4(14.8)	4(16.7)	8(15.7)
Queensland	4(14.8)	4(16.7)	8(15.7)
South Australia	0	3(12.5)	3(5.9)
Victoria	12(44.4)	10(41.7)	22(43.1)
Western Australia	3(11.1)	2(08.3)	5(9.8)
Language other than English	2(7.4)	5(20.8)	7(13.7)
Completed higher education	15(55.6)	14(58.3)	29(56.9)
High distress (K10>19)	21(77.8)	18(75.0)	39(76.5)
Mental Health Literacy	25(92.6)	20(87.0)	51(91.1)
Issues			
Depression	14(51.9)	19(79.2)	33(64.7)
Relationship problems	12(44.4)	9(37.5)	21(41.2)
Body image	2(7.4)	4(16.7)	6(11.8)
Alcohol/drug use	2(7.4)	1(4.2)	3(5.9)
Bullying	0	2(8.3)	2(3.9)
University / school*	10(37.0)	12(50.0)	22(43.1)
Financial issues*	5(18.5)	10(41.7)	15(29.4)
Physical/chronic illness*	2(7.4)	6(25.0)	8(15.7)
Concerns about the future*	3(11.1)	4(16.7)	7(13.7)
Employment issues*	5(18.5)	4(16.7)	9(17.6)
Trauma*	3(11.1)	1(4.2)	4(7.8)
Other*	4(14.8)	7(29.2)	11(21.6)

^{*}Participants' self-reported issues which were not listed in the intervention.

Note: More than one issue could be selected. Issues were coded from open-ended statements hence participants could write as many issues as applied. The Other category included life and communication skills, concern for another person's wellbeing, obtaining a driver's licence, parenting and sexuality.

Of the seven issues included in *Link*, participants reported that they were seeking help for: depression or anxiety, relationship problems, alcohol or drug use, bullying and body image. No participants mentioned self-harm or suicide. In addition, many participants also mentioned issues not covered in *Link* as listed in Table 2. Thirteen participants (21%) only described issues not covered in the program.

Acceptability and feasibility of the intervention and study design

The acceptability and feasibility outcomes are presented in Table 1 with suggested modifications. Three of the four criteria were met for the intervention acceptability and feasibility criteria: no cross-contamination, there were no adverse effects reported, and the *Link* severity scale correlated with psychological distress (K10). The criterion of 85% of intervention participants logging into *Link* was not met, with only 75% doing so. However, 88% of those completing the one-month surveys logged onto *Link*, suggesting that this issue may be a problem of study engagement. Therefore, the intervention was deemed feasible with minor modifications (listed in Table 1) to the study design aimed to increase the number of intervention participants using the intervention.

For the study design, three out of five of the criteria were met: most eligible participants enrolled in the study; the randomisation process produced similar groups; and the expected completion rate was exceeded. The two criteria not met were the time it took to recruit participants and the usefulness of the measures used with minot modifications listed in Table 1.

Secondary outcomes

Summary statistics of the measures used in the baseline and one-month surveys are presented in Table 3 in order to examine the acceptability and feasibility of using these measures in the main trial. No inferential statistics are reported due to the small sample size.

Table 3. Baseline and one-month follow up scores for help-seeking measures.

			C	
	Cor	ntrol	Li	nk
	Baseline	One-Month	Baseline	One-month
	(N = 27)	(N = 20)	(N = 24)	(n = 17)
Resources	n(%)	n(%)	n(%)	n(%)
Face to face	22(81.50)	25(92.60)	20(83.30)	21(87.50)
Online	11(40.70)	14(70.00)	8(33.30)	8(47.10)
None	4(14.80)	2(15.40)	3(12.50)	2(25.00)
	M(SD)	M(SD)	M(SD)	M(SD)
Distress(K10)	27.6(9.36)	25.4(9.78)	28.1(9.07)	24.4(7.06)
General Help Seeking Questionnaire				
Total	3.85(0.81)	4.06(0.85)	3.73(0.92)	3.85(0.62)
Professional	3.69(1.29)	3.88(1.42)	3.26(1.53)	3.47(1.21)
Personal	3.67(1.27)	4.1(1.19)	4.11(1.12)	4.33(0.86)
Online	4.57(1.45)	4.35(1.28)	3.71(1.50)	3.41(1.45)
None	2.3(1.32)	2.7(1.78)	2.75(1.82)	2.06(1.48)
Stages Of Change Questionnaire	ì	` ′	` ′	` ,
Pre-contemplation	1.72(0.44)	1.78(0.49)	1.91(0.23)	1.36(0.42)
Contemplation	,	` /	, ,	2.65(0.41)
Action		2.9(0.66)	, ,	3.51(0.40)
Maintenance		2.32(0.57)	, ,	2.49(0.50)
I want to seek help	`	` /	, ,	3.67(1.01)
I intend to seek help	` ′	` ′	, ,	3.41(1.12)
Barriers to Adolescent Help Seeking	` /		, ,	34.94(6.91)
Mental health help seeking perception	` /		, ,	, ,
Adolescent Quality of Life	0.5(0.11)	0.47(0.13)	, ,	0.54(0.08)
	, ,	···	` '	

There were no notable differences between groups (partial $\eta^2 < 0.1$) except for a small effect in the pre-contemplation scale of the Stages of Change Questionnaire (partial $\eta^2 = 0.4$), with favourable results for the control group.

Satisfaction, trust and whether the participants' expectations were met for the help-seeking strategies are presented in Table 4. Intervention participants reported more satisfaction, expectations met and trust at post-test and satisfaction at one-month compared to the control group (small effect sizes). There were no differences between groups for expectations met or trust at one-month follow up.

Table 4. Participants' satisfaction, trust and whether their expectations were met.

Control $(n = 27)$	Intervention $(n = 24)$	Effect size
M(SD)	M(SD)	d^*
19.52(5.09)	20.75(4.00)	0.3
32.14(6.75)	34.20(4.21)	0.4
3.38(0.80)	3.55(0.69)	0.2
22.40(4.15)	21.71(4.36)	0.2
35.50(7.90)	34.41(7.86)	0.1
3.90(0.72)	3.82(0.73)	0.1
	M(SD) 19.52(5.09) 32.14(6.75) 3.38(0.80) 22.40(4.15) 35.50(7.90)	M(SD) M(SD) 19.52(5.09) 20.75(4.00) 32.14(6.75) 34.20(4.21) 3.38(0.80) 3.55(0.69) 22.40(4.15) 21.71(4.36) 35.50(7.90) 34.41(7.86)

^{*}Effect sizes are based on bootstrapped SD. A value between 0.2 and 0.5 is considered a small effect.

The usefulness of the Link severity scale

We compared the *Link* severity scale with K10 scores. A positive linear relationship (r=0.81) between the *Link* severity scale and the baseline scores of K10 was found (Figure 4).

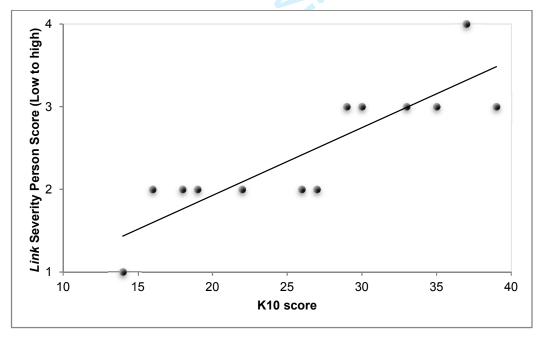


Figure 4. A scatterplot comparison of the *Link* severity scale with the Baseline K10 scores with linear trend line.

Further examination of the qualitative responses revealed that participants in the *Link* intervention arm thought it was a useful program. In particular, the majority of participants in the *Link* arm found that it was quick, easy, self-directed, personalised and had lots of resources.

Some participants had specific problems (e.g., chronic illness, financial, pregnancy, worry about the future) that were not addressed in *Link*, commenting that the information was not appropriate (Female, 19), not understandable (Female, 21), impersonal (Female, 19 and female 21), or too long (Female, 23). Lack of trust in the accuracy of the information available on the internet was also a general concern for both the *Link* and control arms.

DISCUSSION

This Phase II study explored the acceptability and feasibility of the study procedures to be used in the main randomised control trial of *Link*, an online program to assist young adults seeking help for mental health problems. The results demonstrated that the study procedure, involving online surveys and the internet intervention, were feasible and acceptable with several minor modifications identified to enhance the probability of success in the larger trial. There were no indications that the *Link* or the Google arm caused harms in the participants.

Acceptability and feasibility of the intervention and study design

Of the nine acceptability and feasibility criteria, three (logging onto and completing the intervention, recruitment rates, and usefulness of the surveys) were not met. These outcomes were examined to determine likely modifications to successfully meet the criteria in the larger trial and are described below.

Will intervention participants complete Link at least once?

As the number of intervention participants who completed the intervention fell short of the expected number (75% instead of 85%), we will increase the visibility of the link to the intervention program and email reminders to participants to complete the program. Likewise, control participants will receive reminders to seek help using their usual strategies. As 88% intervention participants completed the one-month survey

also completed the intervention program, we anticipate that this minor modification is sufficient to increase numbers.

Can we recruit quickly enough using social media?

Two hundred 18-25 year olds living in Australia were needed to ensure 60 who would participate in the study. As the time frame for completing the study was limited by funding, it was necessary that this number was reached within three months. However, only 143 participants were recruited within a 15-week period. Therefore, three modifications will be implemented in the main trial to improve the recruitment rates including: a new advertising campaign, reducing participant burden and a new reimbursement scheme.

New advertising campaign

Two methods of recruiting were trialled, neither with much success. Further methods of online recruitment are needed to ensure an adequate sample size for the main trial. Using email recruitment from young people signing up to targeted websites (such as ReachOut.com) may increase recruitment rates and will be explored for the main trial. The dynamic nature of recruiting through Google and Facebook became apparent during the first weeks of our study. Due to the competitive nature of social media, flexible advertising with regular monitoring and adjustment is necessary to maintain visibility on social media streams. Increased flexibility of our advertising will increase exposure to young people and also reduce the costs associated with recruiting participants by choosing keywords that aren't currently being used by other organisations. As advertising on social media is dynamic and dependent on other organisations' use of keywords, young people's interests and searches as well as the costs associated with advertising, it is important we respond to the competitive nature of this advertising and have a dynamic and flexible advertising strategy with the ability to change the wording regularly and quickly. As this is a complex and timeconsuming process, we will outsource this recruitment to a professional marketing manager with expertise in marketing and recruitment for research studies.

Reducing participant burden

There was high attrition early in the study procedure indicating that methods to increase retention rates during enrolment into the study are necessary. The sign up process was time-consuming and participants may have had concerns about their privacy. To address these issues an email address and a phone number only will be required. Participants were asked to validate the survey on their email account before obtaining access to the baseline survey. Having a direct link to the baseline survey may reduce drop-off at this point. Third, 20% of participants (n = 13) dropped out after completing the baseline survey and before completing the randomisation process, indicating that processes to encourage participants to continue with the study are important here as well. The language used, length of the survey and the look of the website may have influenced the retention rates at this step. Further methods are needed to increase these rates such as including regular reminders via email and SMS.

New reimbursement scheme

Alexander et al. suggest that a small upfront payment with a higher incentive awarded for retention can increase recruitment and retention rates.[38] A AU\$50 gift card was given to each participant who completed each survey. In order to reduce attrition rates early in the study procedure, rather than the AU\$50 gift card received at the end of the study, an incremental reimbursement schedule will be implemented with participants receiving increasing amounts per survey (e.g., \$10 for baseline, \$15 after post-intervention survey and \$25 after 1-month survey).

Were the measures in the survey useful?

We included a large number of measures in the Phase II trial to explore their usefulness with the understanding that only the most relevant would be retained in the main trial. We found that the K10, the General Help Seeking Questionnaire, the Stages of Change Questionnaire, the Barriers to Adolescent Help Seeking scale, the Adolescent Quality of Life scale and the Client Satisfaction Questionnaire were the most meaningful. Qualitative analyses suggest that participants found the surveys too time-consuming, therefore shortening the surveys is likely to increase completion rates. As the surveys were lengthy, several measures that provided less meaningful results will be removed for the larger trial including the mental health literacy scale and the created items based on the Research-Based Education and Quality Improvement guidelines. These measures are not well validated and are not primary

outcomes so removing them will improve the study design and is anticipated to improve retention in the study.

One of the benefits reported by participants in the qualitative responses was the immediate increase in positive affect after seeking help using *Link*. Therefore, the Positive and Negative Affect Schedule will be used to assess positive affect.[39] Furthermore, as help-seeking is likely to have an immediate impact on young people, rather than a one-week post-intervention survey, participants will be asked to complete the post-intervention as soon as they seek help.

While no differences between groups was anticipated due to the nature of this study, providing control participants with the link to Google may have suggested this avenue of help-seeking and led participants to a help-seeking method not ordinarily in their repertoire. Furthermore, as Google is a well-developed program with years of programing to perfect the search engine, it is highly advanced compared to the *Link* prototype which currently only maps pathways for seven issues and includes 31 services. Therefore, the control arm in the larger trial will exclude the link to Google and direct control participants to use their usual strategies for seeking help.

The *Link* severity scale

Of interest, this study presents some validation for the severity scale used in *Link*, as it consistently correlated with scores on the K10. This suggests that the *Link* severity scale may be a valid measure of the impact of mental health problems on daily life and therefore will be retained within the *Link* intervention.

Secondary outcomes

As discussed above several measures will be removed from the larger trial and the outcome of positive affect will be used as a primary outcome. Some of the current measures used (Stages of Change Questionnaire, The Brief Barriers to Adolescent Help-seeking, General Help Seeking Questionnaire) are not well validated and therefore, while useful as secondary outcomes, are not suitable as a primary outcome. The Mental Health Care Resource Use Questionnaire was also useful and necessary as a secondary outcome, however as the aim of *Link* is to direct young people to services appropriate to their needs and preferences, it is difficult to interpret from the services

used whether this has occurred. An increase in service use is not necessarily useful for participants with low mental health care needs for example.

One of the benefits of online help-seeking strategies is that information is immediately available and the sense of relief felt by participants once an avenue of help is suggested. Participants indicated that they found *Link* helpful and easy to use. Providing avenues of care to participants may increase positive emotions and broaden personal resources for coping and help-seeking. Some of the features of *Link* based on the Theory of Planned Behaviour also tap into the concept of positive psychology.[40] Increasing mental health literacy and providing young people with a sense of empowerment and meaning improves coping skills,[40] particularly problem-focused coping such as help-seeking. By providing avenues for help-seeking in *Link*, in line with the Theory of Planned Behaviour, positive emotions are likely to occur leading to a positive experience of seeking help. Therefore we expect that positive affect, as measured by the Positive Affect Negative Affect Schedule, will be a useful primary outcome.[39] This measure is well-validated and likely to mediate the relationship between beliefs, and help-seeking intentions and behaviours.

Many coping strategies that increase positive affect are integrated in *Link* such as: positive reappraisal; goal-directed problem-focused coping; increasing the repertoire of coping strategies; relaxation and behavioural therapies; and increasing positive meaning of issues.[40–42] In line with this theory, *Link* aims to increase connections with others, improve distraction skills, and increase self-esteem. Furthermore, positive emotions also improve coping skills and increase the likelihood of future emotional well-being.[43]

CONCLUSIONS

In this Phase II trial, we found that the proposed study design and the *Link* intervention were feasible and acceptable to participants with some modifications. These will mainly include improving the recruitment strategies, lessening the burden on participants during sign-up and by shortening the surveys, choosing a different primary outcome measure to determine positive affect and utilising a more realistic control condition to elicit 'usual help-seeking strategies'. These are important features and processes to consider in developing and implementing a complex intervention. It is difficult to determine from this Phase II trial whether *Link* will effectively improve help-seeking or positive affect; however, incorporating the improvements identified as a result of this study, the main randomised controlled trial will allow us to investigate the effects of *Link* on positive affect and help-seeking.

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Contributors

S. Kauer prepared the materials, analysed the data and drafted the article. L. Sanci and K. Buhagiar obtained the funding. K. Buhagiar and V. Blake oversaw the recruitment process. S. Cotton supervised the study design and statistical analyses. All authors were involved with the study design, critically reviewed drafts and approved the submitted manuscript.

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Competing interests

None

CLINICAL REGISTRATION:

This study is reported following the CONSORT guidelines.[23] The study was registered with the Australian New Zealand Clinical Trials Registry (Ref #.: ACTRN12614000386639).

Ethics Approval

This study was approved by the University of Melbourne Human Research Ethics Committee, reference no. 1341063.4.

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Appendix A

Mental Health Help Seeking Perceptions

These questions assesses whether participants know anyone who has sought help for mental health problems and what they perceive this person's help-seeking experience to be like. This is to better understand whether participants have a positive or negative view of mental health help-seeking generally.

- 1. How many people do you know that have sought professional help for mental health or emotional problems?
- Thinking of the person you are closest to...
 How close are you to this person? Very close, Quite close, Sort of close, Not very close, Not close at all.
- 3. Where did this people go to find help (e.g GP, mental health specialist, phone helpline)?
- 4. To your knowledge, how would you rate this person's experience with the professional? Unsure, Very positive/helpful, Somewhat positive/helpful, Neutral, Somwhat negative/unhelpful, Very negative/unhelpful.

Figure A1. Questions about mental health help-seeking perceptions.

Expectations Met Questionnaire

These questions were adapted from Retolaza (2003) about whether their expectations were met in the post-test and one-month follow-up surveys. The language was adapted for use in online settings rather than face-to-face. These items (listed in Figure A.1) were scored from 1 (strongly disagree) to 5 (strongly agree). The measure is summed with a range from 10 to 50.

When thinking about the help-seeking strategy you used, how much do you agree

with the following statements?

- 1. My search helped me make decisions about my mental health
- 2. I found information about services or resources that was helpful
- 3. I understood the information
- 4. My questions were answered
- 5. I found treatment for my problem
- 6. My symptoms or problems improved
- 7. I was guided to seek help from an appropriate service
- 8. I felt surer of myself
- 9. My mood was more positive
- 10. Searching for help this way helped me understand my problems better

Figure A2. The items in the adapted Retolaza form.





CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and	2a	Scientific background and explanation of rationale	4
objectives	2b	Specific objectives or hypotheses	4-5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	5-6
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8-9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	5
•	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence	8a	Method used to generate the random allocation sequence	6
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	6

CONSORT 2010 checklist

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	4.41	assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9-10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NA
Results			
Participant flow (a	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and	11-12
diagram is strongly		were analysed for the primary outcome	
recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	11-12
Recruitment	14a	Dates defining the periods of recruitment and follow-up	10
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	15
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was	17-18
		by original assigned groups	
Outcomes and	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its	17-18
estimation		precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	13
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	22-23
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	5
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	20-23
Other information			
Registration	23	Registration number and name of trial registry	24
Protocol	24	Where the full trial protocol can be accessed, if available	24
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	24

recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CONSORT 2010 checklist Page 2

BMJ Open

Facilitating mental health help-seeking by young adults with a dedicated online program: a feasibility study of Link

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Facilitating mental health help-seeking by young adults with a dedicated online program: a feasibility study of *Link*

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ABSTRACT

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Objective: To explore the feasibility of a dedicated online youth mental health helpseeking intervention, and evaluate using a randomised controlled trial (RCT) study design, in order to identify any modifications needed before commencement of the full scale RCT.

Design: A pilot RCT with 1:1 randomisation to either the intervention or comparison arm.

Setting: An online study conducted Australia-wide.

Participants: 18–25 year-olds living in Australia were recruited via social media.

Intervention: *Link* is a dedicated online mental health help-seeking navigation tool that matches user's mental health issues, severity and service-type preferences (online, phone and face-to-face) with appropriate youth-friendly services. The comparison arm was usual help-seeking strategies with a link to google.com.

Main outcome measures: The primary outcome was the number of acceptability and feasibility criteria successfully met. Intervention and study design acceptability and feasibility were assessed by nine criteria. Secondary outcomes, via online surveys (at baseline, 1-week and 1-month) measured service use, help-seeking intentions, psychological distress, barriers to help seeking, attitudes towards mental health helpseeking, mental health literacy, satisfaction and trust.

Results: Fifty-one participants were randomised (intervention n=24; comparison n=27). Three out of four of the intervention and two out of five of the study design criteria were met. Unmet criteria could be addressed by modifications to the study design. Qualitative analysis demonstrated that Link was useful to participants and may have increased their positive experiences towards help-seeking. There were no observable differences between arms in any outcome measures and no harms were detected.

Conclusion: Generally, the *Link intervention* and study design were acceptable and feasible with modifications suggested for the four out of nine unmet criteria. The main trial will hence have shorter surveys and a simpler recruitment process, use positive affect as the primary outcome and will not link to Google.com for the comparison arm.

Strengths and limitations of this study:

- This study provides important insights into the feasibility of a unique internet intervention for mental health help-seeking for young adults and the study design in preparation for a full scale RCT.
- The study uses social media as an innovative technique to recruit 18-24 year olds across Australia, reflecting how young adults would learn about the intervention in a real-world scenario.

- Following the Medical Research Council's complex intervention guidelines, the intervention is underpinned by a sound theoretical framework ensuring that the design matches the intended goals.
- General practitioners, psychological experts, other service providers, technical
 experts, and young adults were involved in a process of co-design to develop
 the *Link* intervention.
- This pilot study was not powered to assess the statistical significance of the
 outcomes and as such the results are descriptive, not generalisable, and should
 be interpreted with caution.

INTRODUCTION

 Mental health disorders account for the highest burden of disease in adolescence and young adulthood.[1] Up to one quarter of young people experience mental health problems with substantial negative effects on interpersonal relationships, functioning at school and work, general health and wellbeing.[2] Whilst there has been significant investment in mental health service promotion and delivery over the last decade,[3] only 35% of young people experiencing mental health problems seek professional help.[4,5]

The major barriers preventing young people from seeking help include lack of recognition of mental health problems,[6] lack of awareness about appropriate mental health services,[7,8] not being ready to seek help,[2] lack of clinical detection,[9] and the stigma associated with mental illness and seeking professional help.[10]

Facilitated access to treatment services is necessary to improve mental health outcomes,[11] particularly interventions aimed at increasing young people's willingness or readiness to seek help.[12] The international Delphi panel on mental disorders suggested technological solutions may improve treatments, access to care, and advance prevention and early intervention strategies.[13] Young people find information and access mental health services on the internet, and often prefer anonymous sources of help to traditional services.[14–16] Yet, young people report that the help-seeking journey can be complex and repetitive.[17] Non-dedicated search engines such as Google, while providing a vast array of information and sources, do not discern which services are appropriate for young people, and may provide inaccurate and misleading advice and information.[17] Furthermore, help-seeking outcomes associated with existing websites, search engines and dedicated online interventions are rarely evaluated.[18,19]

There is a paucity of evidence for online help seeking interventions and where there are studies, they are poorly designed.[19] We sought to address this gap with a rigorous process, following the guidance of the Medical Research Council (MRC), involving an iterative approach across intervention development, feasibility testing, and evaluation using a randomised trial, before further study on widespread implementation.[20] Help-seeking is a complex behaviour to influence and designing

 an intervention aimed at improving help-seeking online must address multiple components of behaviour change including overcoming barriers to change, as well as providing algorithms to cluster user's symptoms into related condition categories and thereby direct users to appropriate services likely to meet their needs. Our intervention, *Link*, is an online program aimed at facilitating mental health help-seeking for young adults aged 18 to 25 years of age. Our prior development phase examined several theories of help-seeking and behaviour change to determine a suitable theoretical framework with the Theory of Planned Behaviour selected.[21] Secondly, an iterative co-design process with young adults (end users), health service providers, and clinical experts tailored the program for use with young adults seeking help for mental health issues.[17]

In this paper we report on the feasibility study which aimed to: (i) assess the acceptability and feasibility of the online intervention, *Link*, to guide young people to appropriate mental health care or information; (ii) assess the acceptability and feasibility of the study design for the future full scale RCT evaluation; and (iii) identify any modifications needed to the intervention or the study design before proceeding to the main trial. This pilot was essential to ensure that the intervention elements were acceptable, appropriate, and functioned optimally and that the study design was feasible, including the recruitment and randomisation strategy, suitability of the outcome measures, and choice of the primary outcome measure for assessing effectiveness and cost-effectiveness in the future RCT. This feasibility study was not powered to assess the statistical significance of changes in the intervention versus comparison arm, and as such results are descriptive, not generalisable, and should be interpreted with caution.

METHODS

Study Design

A two-arm randomised controlled trial was undertaken. Individuals were baseline tested then randomised into balanced (1:1) parallel arms, the intervention arm (*Link*) or the comparison arm ('usual search strategies'), and then measured for primary and secondary outcomes with surveys at one week and one month post-randomisation. Online recruitment and online surveys were used. The online survey service, QuON,[22] provided a secure server for managing the trial phases, issuing surveys,

and collecting data with responses de-identified and stored securely at the University of Newcastle, Australia. This study is reported following the CONSORT guidelines.[23]

Participants

Recruitment

Two recruitment methods were trialled using various social media and online platforms such as GoogleAds, Facebook advertising, and Gumtree: (1) a static advertising campaign with eight advertisements coupled with keywords; and (2) a dynamic advertising campaign, where advertisements were regularly modified to maintain a high profile and visibility on the various platforms. Advertisements were limited to those living in Australia (for all platforms) and aged between 18 and 25 years (only Facebook allowed specification of age). This online recruitment strategy was used to reach the population most likely to use the intervention in the real world and to emulate how the intervention would be advertised if found to be effective. Online recruitment was chosen over traditional mass media or mail-out campaigns as it has been found to be as representative as mass-media campaigns.[24,25] Further advantages include being able to reach large numbers of participants quickly, a less confrontational format as there is no face-to-face contact, and ease of participation with a click of a button.[26] Recruitment using Facebook has been previously successful with this demographic.[27]

Inclusion Criteria

In keeping with the intention of the *Link* intervention to provide a range of mental health service and information options according to a stepped care approach,[28] the inclusion criteria were broad to encompass young adults with mild distress through to more severe mental health problems who have and have not previously sought help, and young people with or without clinical distress, seeking help for issues such as exam stress, relationship troubles, sleep or bullying. Young people had to be: (1) 18 to 25 years of age; (2) living in Australia; (3) able to provide three contact details such as a current valid email address and residential address and either a phone number or alternative email address; and (4) proficient enough in English to complete the surveys and intervention. Provision of a residential address ensured participants were living in Australia and allowed posting of gift vouchers for participation. The two

other contact details were required to enable follow-up.

Procedure

Young people interested in the study clicked a link in the advertisements and were directed to the study website where a brief explanation of the study was provided along with check boxes confirming eligibility. Those eligible were directed to the information statement which fully explained the study objectives and procedures including the issuing of a \$AUD25 gift voucher on completion of the study. If interested in participating, eligible young people were asked to provide their contact details and to tick a box indicating consent to participation. The online system then issued an email to consenting participants instructing them to verify that the email address was correct. They were then directed to complete the baseline (prerandomisation) survey using their email address as a username to ensure participants could only participate once. Participants chose their own password. During this pilot, it became clear that many participants discontinued their participation at the email verification stage and hence this step was removed (June 13th, one month into the pilot) with consenting participants instead progressing straight to the baseline survey. In addition the information about gift vouchers was moved to the brief explanation page on which participants landed from the recruitment advertisements, in an effort to improve recruitment. Following the baseline survey, participants were randomised into either the intervention or comparison arm. One week and one month postrandomisation measurement surveys were conducted in both arms.

Sample Size

Consistent with feasibility studies, no power analyses were conducted as this study was not intended to assess effectiveness of the intervention relative to the comparison arm. We anticipated that a total sample size of 120 participants (60 in each arm) would be sufficient to test acceptability and feasibility, allowing for approximately 50% attrition, as is common in online recruitment strategies,[29] to ultimately reach a sample of 60 (30 in each arm) at the one-week timepoint.

Randomisation

An independent academic oversaw the randomisation process including generating the sequence for the random allocation using a random seed generator within QuON in random blocks of four, six or eight. Participants were randomly allocated to a trial arm after baseline and identified by a randomly allocated identification number. The researchers were blind to the randomisation sequence until data analysis had been carried out. Participants were emailed a link to either google.com (comparison) or *Link* (intervention) and therefore it was not feasible to blind participants.

Interventions

 Comparison Arm: Usual help-seeking strategies

Participants allocated to the comparison arm received the following instructions: "Please search for information and help for an issue you are currently facing using whatever strategies you would normally use whether it's online or offline. The below link will direct you to www.google.com to begin your search".

The *Link* Intervention Arm

Participants allocated to the intervention arm were asked to seek help using *Link*, comprising three steps in a self-directed triage process (Figure 1): (i) *select issues* (depression/anxiety, body image, drugs/alcohol, self-harm, suicide, bullying, and relationship problems), (ii) *indicate severity* on the *Link severity scale* (setting a level on an interactive pictorial sliding scale on a five-point scale to indicate level of severity from 'I'm OK', 'It's no big deal', 'It's a lot to handle', 'It's really tough' and 'It's a huge deal'), and; (iii) *select service preference* (face-to-face, phone helpline, online chat or email therapy, or online information).

Figure 1 here

Three services appropriate to these specified needs and preferences were then presented with the following information: a description of the service, what to expect, costs and a link for direct access to the service. A 'recommended' service, in addition to the participants' preferred service type was also displayed, based on clinical need. For example, a participant selecting suicidal thoughts as an issue with a preference for online help would also be recommended a 24-hour crisis telephone service ('Lifeline') in addition to their preferred service type. There were 31 youth-friendly

services included in the *Link* directory. The program took a minimum of 30 seconds to complete (in order to reduce attrition during the program), but participants could spend longer exploring their issues or return at a later time to where they had ended a previous session if they wished. Intervention participants had access to *Link* for the duration of the trial (one month in total). For the purposes of this study, participants accessed *Link* using their logon details to link their data with survey data. The development and prototype of the intervention is further described in another publication.[21]

Measures

Primary outcome

Based on previously used criteria,[30] acceptability and feasibility of the intervention and study design are outlined in Table 1; four criteria were used to assess the intervention and five criteria to assess the study design. Based on the number of criteria met, the study design or intervention were deemed 'not feasible' if no criteria were met, 'feasible with modifications' if some of the criteria were met, provided that modifications were possible, and 'feasible with no changes' if all the criteria were met.

Secondary outcomes

Help-seeking behaviours were assessed using the Mental Health Care Resource Use Questionnaire;[31] help-seeking intentions with the Stages of Change Questionnaire (range=1-4), with higher values indicating higher levels;[32] the General Help Seeking Questionnaire (range 1-7), with higher values indicating increased likelihood of seeking help;[33] and two items created ('I want to seek help for my problems' and 'I intend to seek help for my problems)' using the Research-Based Education and Quality Improvement guidelines (range=1-7), with higher values indicating a higher level of intention.[34] We assessed mental health with the Kessler Psychological Distress Scale (K10) (range=5-50), with higher values indicating higher psychological distress;[35] barriers to help-seeking with the Barriers to Adolescents Seeking Help scale (range=11-66), with higher scores indicating more barriers;[7,36] quality of life with the Adolescent Quality of Life Scale;[37] mental health help-seeking perceptions with four created items (Appendix A, Figure A1) ranging from 4-28, with higher scores indicating positive perceptions; and mental health literacy using the Mental Health Literacy Vignette.[38]

Further assessments at the one-week and one-month surveys included: Satisfaction and trust in the service and the likelihood of using the service again using the Client Satisfaction Questionnaire (range=8-40), with higher scores indicating higher satisfaction;[39] whether expectations were met using ten items adapted from Retolaza and Grandes (Appendix A, Figure A2) ranging from 10-50, with higher scores indicating more expectations met;[40] and general feedback with four openended questions (What did you most like/dislike about the program? Do you have any suggestions for improvements? General comments.)

The baseline surveys included all measures except for the questions about satisfaction and trust. The one-week survey included only the questions about satisfaction and trust. The one-month survey included all measures except measures of mental health literacy and perceptions.

Data Management and analysis

 Data from the online surveys and pathways through the *Link* intervention were collected into QuON. The Stata statistical package Version 13 was used for data analysis.[41] The primary outcome was the number of acceptability and feasibility items that were met. Descriptive statistics were used to describe the secondary

outcomes. Effect sizes (Cohen's d) were calculated using bootstrapped standard deviations for the satisfaction and trust questions. For all other continuous outcomes, multiple regression analyses were performed in order to calculate post-estimation effect sizes; however, these are not reported due to the small sample size.

RESULTS

Study procedure

Figure 2 illustrates the participant flow throughout the study. The static advertising campaign ran from the 7th May to 12th June 2014 with a total of 23 participants randomised during these five weeks. Next, the dynamic campaign was used from 13th June to 19th August 2014 with a total of 28 participants randomised within this eleven-week period. The majority of participants (45, 88%) were recruited via Facebook advertising.

** Figure 2 here **

Of the 24 participants allocated to the intervention group, 18 (75%) accessed *Link*. Only two participants (11.8%) who completed the one-month follow-up assessment did not access Link.

Retention and assessment procedures

Once participants were randomised into the study, attrition rates reduced. From the 51 randomised, only six participants (11.8%; three from each arm) did not complete either of the surveys post-intervention and were unable to be included in the outcome analysis. A further three (5.9%) did not complete the one-week survey and six (11.8%) did not complete the one-month survey, leaving a total of 34 (66.7%) participants with complete data.

1 Table 1. Acceptability and feasibility criteria, outcomes and contingency plans

Questions	Criteria	Met?	Outcomes and contingency plan
Acceptability and feasibility of the inter	rvention		
Will intervention participants complete <i>Link</i> at least once?	85% of participants log on at least once	No	18/24 (75%) accessed the intervention. However, 15/17 (88%) of those completing the 1-month assessment accessed the intervention. As well as emailing arm allocation to participants, the last page of the baseline survey will contain a link to the allocated intervention so participants can immediately and directly log onto the comparison condition or Link without checking their email account to access the link to their allocation. Another strategy to increase intervention access will be to send reminder emails containing the link to the allocation status and to expand the issues addressed by <i>Link</i> to include some of the issues indicated with a * in Table 2.
Will there be any cross-contamination between arms?	No comparison participants use the intervention	Yes	0/27 comparison participants logged on to the intervention.
Did the intervention cause harm?	No serious negative reports or feedback	Yes	There were no negative reports.
Is the severity rating on the intervention useful? Acceptability and feasibility of study de	The severity rating correlates with level of distress (k10) by at least .6 sign and procedures	Yes	The correlation between severity and k10 = 0.69.
Can we recruit quickly enough using social media?	200 eligible participants reached within three months	No	320/2751 (7%) who saw the advertisement completed the inclusion criteria. 49/192 (26%) who did complete the criteria were ineligible, leaving a total of 143 young adults recruited in a 15-week period, three weeks longer than anticipated. As a result: 1. a new advertising campaign will be implemented including electronic direct mail, outsourced to a professional marketing manager, with weekly monitoring to adjust the language used in the ads and the keywords depending on the searches and interests of young people, other organisations using the keywords, and the costs associated with the keywords; 2. the burden of participation will be reduced by re-designing the sign-up process and shortening the surveys; 3. a new incentive scheme will be devised involving increasing the amount awarded to participants based on the number of surveys completed.
Were the measures in the survey useful?	All measures produce a meaningful and unique score	No	Some of the measures were qualitative in nature and difficult to interpret across a larger group of participants, including the mental health literacy measure and the perceptions of mental health items. The length of the survey, particularly due to these items, possibly contributed to attrition rates. After further discussion with the research team, young people and clinicians, changes in survey measures will be undertaken for the future RCT. The mental health literacy and perceptions of mental health items will not be included in the main trial. Given the theoretical considerations of how the <i>Link</i> intervention might work to relieve young

Do most eligible participants enrol into study?	80% of eligible participants completed the baseline and randomisation process	No
study:	baseline and randomisation process	
Did the randomisation process work?	Equal numbers of participants in each group	Yes
Was the loss to follow-up reasonable?	(within 10%) with similar demographics At least half of the participants completing all	Yes
•		

surveys

people's immediate distress when they realise there are options to address their mental health concerns, an additional measure of positive and negative affect, immediately post-intervention will be used as a primary outcome for the main trial. The comparison condition will not include a link to Google.com in the main trial as this was suggesting a strategy rather than young people's 'usual strategies' which may not include online. In addition it was felt that landing participants on the Google.com search page presented an unfair comparison condition as the prototype of *Link* was narrower in the scope of issues capable of being addressed compared to Google.com. Google.com may also present misleading information as search results are not vetted.

136/320 (42.5%) did not complete the inclusion criteria or consent to participate. This may have been due to the number of contact details requested. A further 61/184 (33.2%) participants did not verify their email address and begin the baseline survey.

13/64 (20.3%) dropped out during the baseline survey before completing the randomisation process.

Less contact details will be requested to improve the consent process.

The verification of email will be removed allowing participants to begin the baseline survey more quickly. Feedback from participants indicated that the survey was too long. To further increase completion rates, surveys will be shorter.

27/51 (52.9%) were allocated to the comparison arm and 24/51 (47.1%) were allocated to the Link intervention arm.

34/51 (67%) completed all surveys.

To further increase completion rates, surveys will be shorter.

Baseline data

The mean age of participants was 20.9 years (Intervention: M=20.9, SD=2.1; Comparison: M=21.0, SD=1.9). Other baseline characteristics are listed in Table 2 by arm. There were no differences between groups using chi-squared (χ^2) and independent samples t-test statistics.

Table 2. Baseline characteristics by arm

	Comparison	Link	Total	
	(N = 27)	(N = 24)	(N = 51)	
	n(%)	n(%)	n(%)	
Female	22(81.5)	17(70.8)	39(76.5)	
Rural	9(3.3)	4(16.7)	13(25.5)	
State				
Australian Capital Territory	4(14.8)	1(4.2)	5(9.8)	
New South Wales	4(14.8)	4(16.7)	8(15.7)	
Queensland	4(14.8)	4(16.7)	8(15.7)	
South Australia	0	3(12.5)	3(5.9)	
Victoria	12(44.4)	10(41.7)	22(43.1)	
Western Australia	3(11.1)	2(8.3)	5(9.8)	
Language other than English	2(7.4)	5(20.8)	7(13.7)	
Completed higher education	15(55.6)	14(58.3)	29(56.9)	
High distress (K10>19)	21(77.8)	18(75.0)	39(76.5)	
Mental Health Literacy	25(92.6)	20(87.0)	51(91.1)	
Issues				
Depression	14(51.9)	19(79.2)	33(64.7)	
Relationship problems	12(44.4)	9(37.5)	21(41.2)	
Body image	2(7.4)	4(16.7)	6(11.8)	
Alcohol/drug use	2(7.4)	1(4.2)	3(5.9)	
Bullying	0	2(8.3)	2(3.9)	
University /school*	10(37.0)	12(50.0)	22(43.1)	
Financial issues*	5(18.5)	10(41.7)	15(29.4)	
Physical/chronic illness*	2(7.4)	6(25.0)	8(15.7)	
Concerns about the future*	3(11.1)	4(16.7)	7(13.7)	
Employment issues*	5(18.5)	4(16.7)	9(17.6)	
Trauma*	3(11.1)	1(4.2)	4(7.8)	
Other*	4(14.8)	7(29.2)	11(21.6)	

^{*}Participants' self-reported issues which were not listed in the intervention.

Note: More than one issue could be selected. Issues were coded from open-ended statements hence participants could write as many issues as applied. The Other category included life and communication skills, concern for another person's wellbeing, obtaining a driver's licence, parenting and sexuality.

Of the seven issues included in Link, participants reported that they were seeking help for: depression or anxiety, relationship problems, alcohol or drug use, bullying and body image. No participants mentioned self-harm or suicide. In addition, many participants also mentioned issues not covered in Link as listed in Table 2. Thirteen participants (21%) only described issues not covered in the program.

Acceptability and feasibility of the intervention and study design

The acceptability and feasibility outcomes are presented in Table 1 with suggested modifications. Three of the four criteria were met for the intervention acceptability and feasibility criteria: no cross-contamination or adverse effects were reported, and the *Link* severity scale correlated with psychological distress (K10). The criterion of 85% of intervention participants logging onto *Link* was not met, with only 75% doing so. However, 88% of those completing the one-month surveys logged onto *Link*, suggesting that failure to utilise *Link* may be a problem of engagement with the study measurement procedure. Therefore, the intervention was deemed feasible with minor modifications (listed in Table 1) to the study design to increase the number of intervention participants using the intervention. It was also planned to expand the scope of pathways included in *Link* to address the other issues people described wanting assistance with (Table 2).

For the study design, two out of five of the criteria were met: the randomisation process produced similar groups; and the expected completion rate was exceeded. The three criteria not met were the time it took to recruit participants, the usefulness of the measures used and enrolment into the study with minor modifications listed (Table 1).

Secondary outcomes

Summary statistics of the measures used in the baseline and one-month surveys are presented in Table 3 in order to examine the acceptability and feasibility of using these measures in the main trial. No inferential statistics are reported due to the small sample size.

Table 3. Baseline and one-month follow up scores for help-seeking measures.

	-	-	_		
	Comparison		Link		
	Baseline	One-Month	Baseline	One-month	
	(N = 27)	(N = 20)			
Resources	n(%)	n(%)	n(%)	n(%)	
Face to face	22(81.50)	25(92.60)	20(83.30)	21(87.50)	
Online	11(40.70)	14(70.00)	8(33.30)	8(47.10)	
None	4(14.80)	2(15.40)	3(12.50)	2(25.00)	
	M(SD)	M(SD)	M(SD)	M(SD)	
Distress(K10)	' /	' /	, ,	24.4(7.06)	
General Help Seeking Questionnaire	27.0(3.30)	20.1(5.70)	20.1(5.07)	21.1(7.00)	
Total	3.85(0.81)	4 06(0 85)	3 73(0 92)	3.85(0.62)	
Professional	3.69(1.29)	` /	` /	3.47(1.21)	
Personal	` /	` /	` /	4.33(0.86)	
Online	, ,	4.35(1.28)		, ,	
None	2.3(1.32)	` ′	2.75(1.82)	` ′	
Stages Of Change Questionnaire	2.0(1.02)	- (1.,0)		2.00(1.10)	
Pre-contemplation	1.72(0.44)	1.78(0.49)	1.91(0.23)	1.36(0.42)	
Contemplation	2.73(0.39)	2.65(0.38)	2.64(0.45)	2.65(0.41)	
Action	3.03(0.52)	2.9(0.66)	3.23(0.75)	3.51(0.40)	
Maintenance		` /	` /	2.49(0.50)	
I want to seek help	3.96(1.02)	3.56(1.12)	3.71(1.04)	3.67(1.01)	
I intend to seek help				3.41(1.12)	
Barriers to Adolescent Help Seeking	37.6(7.39)	36.93(7.32)	34.7(10.10)	34.94(6.91)	
Mental health help seeking perception					
Adolescent Quality of Life	0.5(0.11)	0.47(0.13)	, ,	0.54(0.08)	

There were no notable differences between groups (partial $\eta^2 < 0.1$) except for a small effect in the pre-contemplation scale of the Stages of Change Questionnaire (partial $\eta^2 = 0.4$), with favourable results for the comparison group.

Satisfaction, trust and whether the participants' expectations were met for the help-seeking strategies are presented in Table 4. Intervention participants reported more satisfaction, expectations met and trust at post-test compared to the comparison arm (small effect sizes), with a small effect size favouring the comparison group for satisfaction at one-month. There were no differences between arms for expectations met or trust at one-month follow up.

Table 4. Participants' satisfaction, trust and whether their expectations were met.

	Comparison (n=27)	Link (n = 24)	Effect size
	M(SD)	M(SD)	d^*
One week outcomes			
Satisfaction	19.52(5.09)	20.75(4.00)	0.3
Expectations met	32.14(6.75)	34.20(4.21)	0.4
Trust	3.38(0.80)	3.55(0.69)	0.2
One month outcomes			
Satisfaction	22.40(4.15)	21.71(4.36)	0.2
Expectations met	35.50(7.90)	34.41(7.86)	0.1
Trust	3.90(0.72)	3.82(0.73)	0.1

^{*}Effect sizes are based on bootstrapped SD. A value between 0.2 and 0.5 is considered a small effect.

The usefulness of the *Link* severity scale

We compared the *Link* severity scale with K10 scores. A positive linear relationship (r=0.81) between the *Link* severity scale and the baseline scores of K10 was found (Figure 3).

Figure 3 here

Further examination of the qualitative responses revealed that participants in the *Link* intervention arm thought it was a useful program. In particular, the majority of participants in the *Link* arm found that it was quick, easy, self-directed, personalised and had lots of resources.

Some participants had specific problems (e.g., chronic illness, financial, pregnancy, worry about the future) that were not addressed in *Link*, commenting that the 'information was not appropriate' (female, aged 19), 'not understandable' (female, aged 21), 'impersonal' (females, aged 19 and 21), or 'too long' (female, aged 23). Lack of trust in the accuracy of the information available on the internet was also a general concern for both the *Link* and comparison arms.

DISCUSSION

This feasibility study piloted the acceptability and feasibility of the *Link* intervention and the study procedures to be used in the future RCT of Link, an online program to assist young adults seeking help for mental health problems. The results demonstrated that the study procedure, involving online surveys and the internet intervention, were feasible and acceptable with several minor modifications identified to enhance recruitment, intervention use, and retention in the main trial. There were no indications that the *Link* or the Google arm caused harms in the participants.

Acceptability and feasibility of the intervention and study design

Of the nine acceptability and feasibility criteria, four (logging onto and completing the intervention, recruitment rates, usefulness of the surveys and enrolment rates) were not met. These outcomes were examined to determine likely modifications to successfully meet the criteria in the main trial and are described below.

Will intervention participants complete Link at least once?

As the number of intervention participants who completed the intervention fell short of the expected number (75% instead of 85%), we will increase the visibility of the link to the intervention program in email reminders to participants to complete the program. Likewise, comparison participants will receive reminders to seek help using their usual strategies. As 88% of intervention participants who completed the onemonth survey also completed the intervention program, we anticipate that this minor modification will be sufficient to increase the number of intervention participants who access the *Link* intervention.

Can we recruit quickly enough using social media?

Two hundred 18-25 year olds living in Australia were needed to ensure 60 who would participate in the study. As the time frame for completing the study was limited by funding, it was necessary that this number was reached within three months. However, only 143 participants were recruited within a 15-week period. Therefore, two modifications will be implemented in the main trial to improve the recruitment rates: a new advertising campaign and a new reimbursement scheme.

New advertising campaign

 Two methods of recruiting were trialled in this feasibility study, neither with much success. Further methods of online recruitment are needed to ensure an adequate sample size for the future main trial. Using email recruitment from young people signing up to targeted websites (such as ReachOut.com) may increase recruitment rates and will be explored for the main trial.

The dynamic nature of recruiting through Google and Facebook became apparent during the first weeks of our study. Due to the competitive nature of social media, flexible advertising with regular monitoring and adjustment is necessary to maintain visibility on social media streams. Increased flexibility of our advertising will increase exposure to young people and also reduce the costs associated with recruiting participants by choosing keywords that aren't currently being used by other organisations. As advertising on social media is dynamic, and dependent on other organisations' use of keywords, young people's interests and searches as well as the costs associated with advertising, it is important we respond to the competitive nature of this advertising and have a dynamic and flexible advertising strategy with the ability to change the wording regularly and quickly. As this is a complex and timeconsuming process, we will outsource this recruitment to a professional marketing manager with expertise in marketing and recruitment for research studies.

New reimbursement scheme

Alexander et al. suggest that a small upfront payment with a higher incentive awarded for retention can increase recruitment and retention rates.[42] A \$AUD25 gift card was given to each participant who completed the one month survey. In order to reduce attrition rates early in the study procedure, rather than the AU\$25 gift card received at the end of the study, an incremental reimbursement schedule will be implemented with participants receiving increasing amounts per survey (e.g., \$10 for baseline, \$15 after post-intervention survey and \$25 after a one-month follow-up survey).

Were the measures in the survey useful?

We included a large number of measures in the feasibility trial to explore their usefulness with the understanding that only the most relevant would be retained in the main trial. We found that the K10, the General Help Seeking Questionnaire, the

Stages of Change Questionnaire, the Barriers to Adolescent Help Seeking scale, the Adolescent Quality of Life scale and the Client Satisfaction Questionnaire were the most meaningful. Qualitative analyses suggest that participants found the surveys too time-consuming, therefore shortening the surveys is likely to increase completion rates. Therefore, several measures that provided less meaningful results will be removed for the larger trial including the mental health literacy scale and the items we created based on the Research-Based Education and Quality Improvement guidelines.[34] These measures are not well validated and are not primary outcomes so removing them is anticipated to improve the study design and retention. One of the benefits reported by participants in the qualitative responses was the immediate increase in positive affect after seeking help using *Link*. This outcome was also discussed as a likely first step in engaging young people with a help-seeking journey during participatory workshops with service providers, researchers and young people. Therefore, the Positive and Negative Affect Schedule will be used to assess positive affect after participants have been exposed to their intervention, as the primary outcome.[43]

Do most eligible participants enrol into study?

 There was high attrition early in the study procedure indicating that methods to increase retention rates during enrolment into the study are necessary. The sign up process was time-consuming and participants may have had concerns about their privacy. Hence an email address and a phone number only will be required for the main trial. Participants were asked to validate the survey on their email account before obtaining access to the baseline survey in the beginning of the pilot study. One of the changes made during the pilot study was a direct link to the baseline survey without the email validation process. This may reduce drop-off at this point. Thirdly, 20% of participants (n = 13) dropped out after completing the baseline survey and before completing the randomisation process, indicating that processes to encourage participants to continue with the study are important here as well. The language used, length of the survey and the look of the website may have influenced the retention rates at this step. Further methods are needed to increase these rates such as including regular reminders via email and SMS.

The *Link* severity scale

Of interest, this study presents some validation for the severity scale used in *Link*, as it consistently correlated with scores on the K10. This suggests that the *Link* severity scale may be a valid measure of the impact of mental health problems on daily life and therefore will be retained within the *Link* intervention.

Secondary outcomes

As discussed above several measures will be removed from the larger trial and the outcome of positive affect will be used as a primary outcome. Some of the current measures used (Stages of Change Questionnaire, The Brief Barriers to Adolescent Help-seeking, General Help Seeking Questionnaire) are not well validated and therefore, while useful as secondary outcomes, are not suitable as a primary outcome. The Mental Health Care Resource Use Questionnaire was also useful and necessary as a secondary outcome, however as the aim of *Link* is to direct young people to services appropriate to their needs and preferences, it is difficult to interpret from the services used whether this has occurred. An increase in service use is not necessarily useful for participants with low mental health care needs for example.

One of the benefits of online help-seeking strategies is that information is immediately available and the sense of relief felt by participants once an avenue of help is suggested. Participants indicated that they found *Link* helpful and easy to use. Providing avenues of care to participants may increase positive emotions and broaden personal resources for coping and help-seeking. Some of the features of *Link* based on the Theory of Planned Behaviour also tap into the concept of positive psychology. [44] Increasing mental health literacy and providing young people with a sense of empowerment and meaning improves coping skills, [44] particularly problem-focused coping such as help-seeking. By providing avenues for help-seeking in *Link*, in line with the Theory of Planned Behaviour, positive emotions are likely to occur leading to a positive experience of seeking help. Therefore we expect that positive affect will be an appropriate primary outcome. [43] This measure is well-validated and likely to mediate the relationship between beliefs, and help-seeking intentions and behaviours. Many coping strategies that increase positive affect are reinforced in *Link* such as: positive reappraisal; goal-directed problem-focused coping; increasing the repertoire of coping strategies; relaxation and behavioural therapies; and increasing positive meaning of issues. [44–46] In line with this theory, Link aims to increase connections with others, improve distraction skills, and increase self-esteem. Furthermore, positive emotions also improve coping skills and increase the likelihood of future emotional well-being.[47]

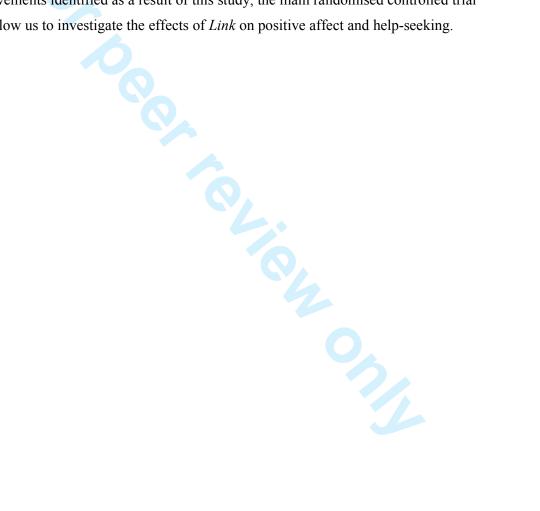
Strengths and Limitations

Conducting this feasibility study was a useful way to optimise the intervention and the study design with many issues uncovered before commencement of the main RCT. There were many strengths including the novel recruitment strategies employed allowing a broad range of young adults to be involved in the study. The online survey, data management and randomisation were generally successful with few issues found. While no differences between arms was anticipated due to the exploratory nature of this study, providing comparison participants with the link to Google was a limitation as it may have suggested this avenue of help-seeking and led participants to a helpseeking method not ordinarily in their repertoire. Furthermore, as Google is a welldeveloped program with years of programing to perfect the search engine, it is highly advanced compared to the Link prototype which currently only maps pathways for seven issues and includes 31 services. Therefore, the comparison arm in the larger trial will exclude the link to Google and instead direct comparison participants to use their usual strategies for seeking help.

A measure of positive and negative affect was not included in this study. This outcome is a key element to mental health help-seeking, as positive affect associated with the act of help-seeking is important to continued help-seeking behaviour and obtaining help if needed. Many of the outcome measures used are not well validated or widely used. This is in part due to the small number of publications in the field, but also because of the complexity of mental health 'help-seeking' as a focus compared to mental health, or psychological distress.

CONCLUSIONS

In this feasibility study, we found that the proposed study design and the *Link* intervention were feasible and acceptable to participants with some modifications. These will mainly include improving the recruitment strategies, lessening the burden on participants during sign-up and by shortening the surveys, choosing a different primary outcome measure to determine positive affect and utilising a more realistic comparison condition to elicit 'usual help-seeking strategies'. These are important features and processes to consider in developing and implementing a complex intervention. It is difficult to determine from this pilot trial whether *Link* will effectively improve help-seeking or positive affect; however, incorporating the improvements identified as a result of this study, the main randomised controlled trial will allow us to investigate the effects of *Link* on positive affect and help-seeking.



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Contributors

S. Kauer prepared the materials, analysed the data and drafted the article. L. Sanci and K. Buhagiar conceptualised the study and obtained the funding. K. Buhagiar and V. Blake oversaw the recruitment process. S. Cotton supervised the study design and statistical analyses. All authors were involved with the study design, critically reviewed drafts and approved the submitted manuscript.

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Competing interests

None

Data sharing

No additional data

CLINICAL REGISTRATION:

This study is reported following the CONSORT guidelines.[23] The study was registered with the Australian New Zealand Clinical Trials Registry (Ref #.: ACTRN12614000386639).

Ethics Approval

This study was approved by the University of Melbourne Human Research Ethics Committee, reference no. 1341063.4. All participants consented to take part in this study via an online consent form.

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Figure Legends

Figure 1. The webpages of Link

Figure 2. The study flow diagram.

* These participants did not complete the one-week survey but completed the one month survey. *Note*: Withdrew before entering study group = Started baseline then withdrew, or completed baseline and withdrew before randomisation.

Figure 3. A scatterplot comparison of the *Link* severity scale with the Baseline K10 scores with linear trend line.

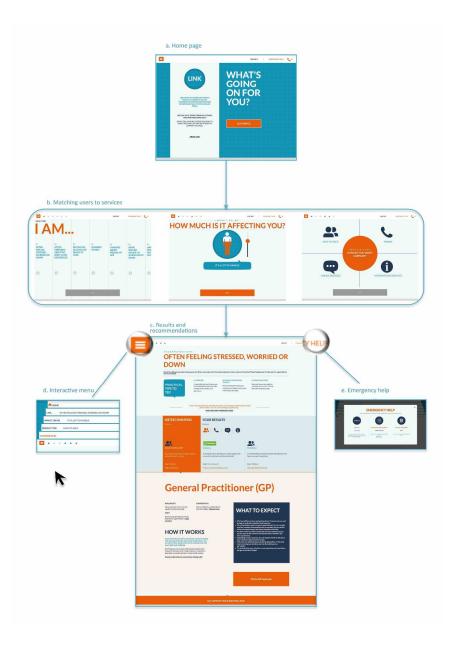


Figure 1. The webpages of Link $263 \times 366 \text{mm} (300 \times 300 \text{ DPI})$

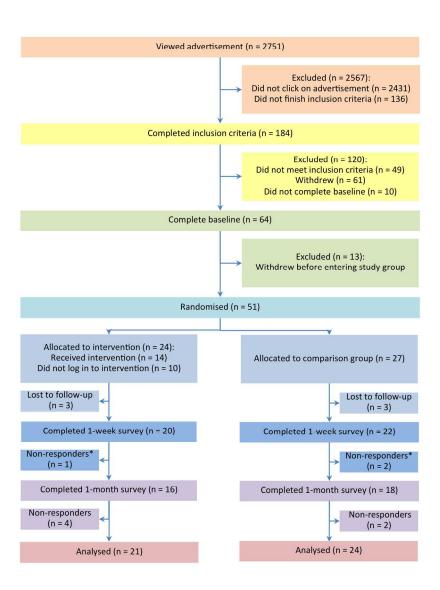


Figure 2. The study flow diagram.

181x222mm (300 x 300 DPI)

^{*} These participants did not complete the one-week survey but completed the one month survey. Note: Withdrew before entering study group = Started baseline then withdrew, or completed baseline and withdrew before randomisation.

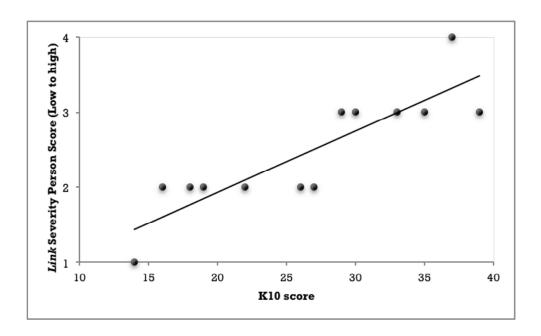


Figure 3. A scatterplot comparison of the Link severity scale with the Baseline K10 scores with linear trend line.

250x154mm (300 x 300 DPI)

Appendix A

Mental Health Help Seeking Perceptions

These questions assesses whether participants know anyone who has sought help for mental health problems and what they perceive this person's help-seeking experience to be like. This is to better understand whether participants have a positive or negative view of mental health help-seeking generally.

- How many people do you know that have sought professional help for mental health or emotional problems?
- Thinking of the person you are closest to...
 How close are you to this person? Very close, Quite close, Sort of close, Not very close, Not close at all.
- 3. Where did this people go to find help (e.g. GP, mental health specialist, phone helpline)?
- 4. To your knowledge, how would you rate this person's experience with the professional? Unsure, Very positive/helpful, Somewhat positive/helpful, Neutral, Somewhat negative/unhelpful, Very negative/unhelpful.

Figure A1. Questions about mental health help-seeking perceptions.

Expectations Met Questionnaire

These questions were adapted from Retolaza and Grandes (2003) about whether their expectations were met in the post-test and one-month follow-up surveys. The language was adapted for use in online settings rather than face-to-face. These items (listed in Figure A.1) were scored from 1 (strongly disagree) to 5 (strongly agree). The measure is summed with a range from 10 to 50.

When thinking about the help-seeking strategy you used, how much do you agree

with the following statements?

- 1. My search helped me make decisions about my mental health
- 2. I found information about services or resources that was helpful
- 3. I understood the information
- 4. My questions were answered
- 5. I found treatment for my problem
- 6. My symptoms or problems improved
- 7. I was guided to seek help from an appropriate service
- 8. I felt surer of myself
- 9. My mood was more positive
- 10. Searching for help this way helped me understand my problems better

Figure A2. The items in the adapted Retolaza form.



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and	2a	Scientific background and explanation of rationale	4
objectives	2b	Specific objectives or hypotheses	4-5
•			
Methods	0	Description of the last of the	_
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
5	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	5-6
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8-9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	5
•	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence	8a	Method used to generate the random allocation sequence	6
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers),	6
concealment mechanism		describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	6

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		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9-10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NA
Results			
Participant flow (a diagram is strongly	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	11-12
recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	11-12
Recruitment	14a	Dates defining the periods of recruitment and follow-up	10
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	15
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	17-18
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	17-18
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	13
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	22-23
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	5
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	20-23
Other information			
Registration	23	Registration number and name of trial registry	24
Protocol	24	Where the full trial protocol can be accessed, if available	24
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	24

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

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