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Citation: Slade, M., Rennick-Egglestone, S., Elliott, R. A., Newby, C., Robinson, C., Gavan, S. P., Paterson, L., Ali, Y., Yeo, C., Glover, T., et al (2024). Effectiveness and cost-effectiveness of online recorded recovery narratives in improving quality of life for people with non-psychotic mental health problems: a pragmatic randomized controlled trial. World Psychiatry, 23(1), pp. 101-112. doi: 10.1002/wps.21176

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Cite as: Slade M, Rennick-Egglestone S, Elliott RA, Newby C, Robinson C, Gavan SP, Paterson L, Ali Y, Yeo C, Glover T, Pollock K, Callard F, Priebe S, Thornicroft G, Repper J, Keppens J, Smuk M, Franklin D, Walcott R, Harrison J, Smith R, Robotham D, Bradstreet S, Gillard S, Cuijpers P, Farkas M, Ben Zeev D, Davidson L, Kotera Y, Roe J, Ng F, Llewellyn-Beardsley J on behalf of the NEON study group *Effectiveness and cost-effectiveness of online recorded recovery narratives in improving quality of life for people with non-psychotic mental health problems: a pragmatic randomized controlled trial*, World Psychiatry, in press.

Effectiveness and cost-effectiveness of online recorded recovery narratives in improving quality of life for people with non-psychotic mental health problems: a pragmatic randomized controlled trial

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Narratives describing first-hand experiences of recovery from mental health problems are widely available. Emerging evidence suggests that engaging with mental health recovery narratives can benefit people experiencing mental health problems, but no randomized controlled trial has been conducted as yet. We developed the Narrative Experiences Online (NEON) Intervention, a web application providing self-guided and recommender systems access to a collection of recorded mental health recovery narratives (n=659). We investigated whether NEON Intervention access benefited adults experiencing non-psychotic mental health problems by conducting a pragmatic parallel-group randomized trial, with usual care as control condition. The primary endpoint was quality of life at week 52 assessed by the Manchester Short Assessment (MANSA). Secondary outcomes were psychological distress, hope, self-efficacy, and meaning in life at week 52. Between March 9, 2020 and March 26, 2021, we recruited 1,023 participants from across England (the target based on power analysis was 994), of whom 827 (80.8%) identified as White British, 811 (79.3%) were female, 586 (57.3%) were employed, and 272 (26.6%) were unemployed. Their mean age was 38.4±13.6 years. Mood and/or anxiety disorders (N=626, 61.2%) and stress-related disorders (N=152, 14.9%) were the most common mental health problems. At week 52, our intention-to-treat analysis found a significant baseline-adjusted difference of 0.13 (95% CI: 0.01-0.26, p=0.041) in the MANSA score between the intervention and control groups, corresponding to a mean change of 1.56 scale points per participant, indicating that the intervention increased quality of life. We also detected a significant baseline-adjusted difference of 0.22 (95% CI: 0.05-0.40, p=0.014) between the groups in the score on the “presence of meaning” subscale of the Meaning in Life Questionnaire, corresponding to a mean change of 1.1 scale points per participant. We found an incremental gain of 0.0142 quality-adjusted life years (QALYs) (95% credible interval: 0.0059 to 0.0226) and a £178 incremental increase in cost (95% credible interval: –£154 to £455) per participant, generating an incremental cost-effectiveness ratio of £12,526 per QALY compared with usual care. This was lower than the £20,000 per QALY threshold used by the National Health Service in England, indicating that the intervention would be a cost-effective use of health service resources. In the subgroup analysis including participants who had used specialist mental health services at baseline, the intervention both reduced cost (–£98, 95% credible interval: –£606 to £309) and improved QALYs (0.0165, 95% credible interval: 0.0057 to 0.0273) per participant as compared to usual care. We conclude that the NEON Intervention is an effective and cost-effective new intervention for people experiencing non-psychotic mental health problems.

Key words: NEON Intervention, recovery narrative, non-psychotic mental health problems, digital health intervention, quality of life, meaning in life, lived experience narrative

Recorded narratives describing personal experiences of mental health problems have been widely used in health care and community settings[1], including in professional training[2] and as a resource in psychotherapy sessions[3]. They have been a central component of national campaigns to reduce mental health stigma[4], where they have been used as a scalable mechanism to create a perception of social contact with people who have experienced mental health problems[5].

Recorded recovery narratives (RRNs) are a specific category of mental health narratives which describe recovery from mental health problems[6]. They are widely available to the public[7], either individually or in collections curated around a common theme, such as books intended to create hope by presenting narratives describing psychosis recovery[8]. They have been widely used to promote mental health recovery[9]. Narrators have described creating hope in others as a motivation for publishing their recovery narrative[10]. However, whilst the benefits to narrators of sharing a narrative are well established[11], the benefits to narrative recipients are under-investigated.

Through a six-year research program (2017-2023), the Narrative Experiences Online (NEON) study has investigated whether access to an online RRN collection can benefit people currently experiencing mental health problems and their informal carers. This has included developing and evaluating the NEON Intervention, a web-based digital health intervention which provides access to a collection of 659 RRNs[12].

The program theory for the NEON Intervention is the NEON Impact model, which was developed from systematic review, interview and experimental evidence[13-16]. In this model, the expected benefit of receiving RRNs is enhanced quality of life through increases in hope, connectedness, empowerment, meaning in life, initiation of help-seeking behaviours, and emulation of helpful narrator behaviours. Possible harms include emotional burden from encountering difficult experiences described in RRNs, and emulation of harmful narrator behaviours. As we developed the NEON Intervention, we selected safety strategies to manage known harms, supported by lived experience and academic advice[12].

Here we report on a pragmatic parallel-group randomized controlled trial of the NEON Intervention across England, which aimed to explore whether receiving online recorded recovery narratives, in addition to usual care, benefits people with experience of non-psychotic mental health problems. The primary objective of the trial was to evaluate the effectiveness of the NEON Intervention in improving quality of life, as compared to usual care only. Secondary objectives were: a) to evaluate the effectiveness of the NEON Intervention in improving hope, empowerment and meaning in life, and in reducing psychological distress, as compared to usual care; b) to assess the cost-effectiveness of the NEON Intervention compared to usual care, from a health and social care provider perspective; c) to determine whether effectiveness and cost-effectiveness varied according to prior health service usage; and d) to understand

how the intervention was used.

Participants were randomly assigned to receive immediate (intervention group) or 52-week delayed (control group) intervention access, were not masked to treatment allocation due to the nature of the intervention, and continued to receive their usual care. The primary objective and the secondary objectives a) and b) were assessed at 52-week follow-up, and their measures were baseline-adjusted.

METHODS

Study overview

We obtained ethical approval for the trial from the Leicester Central Research Ethics Committee (19/EM/0326), and approval for managing the NEON Collection from the West London and Gene Therapy Advisory Committee Research Ethics Committee (18/LO/0991).

The trial was prospectively registered (ISRCTN63197153). A Trial Management Group and an independent Programme Steering Committee provided oversight. All trial procedures and the NEON Intervention were delivered through a web application validated by a feasibility study with mental health service users[12].

The chief investigator (MS), the senior statistician (CR) and the trial statistician (CN) were blinded to treatment allocation. MS and CR remained blind until trial analysis work was completed and approved. The trial protocol[17], the statistical analysis plan[18], the NEON Intervention development and delivery cost[19], and the baseline participant characteristics[20,21] have been previously reported.

Reporting of the results of the trial follows the Consolidated Standards of Reporting Trials (CONSORT) 2010[22] and the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) 2022[23] statements.

Participants

Inclusion criteria, ascertained through an online eligibility-checking interface (see below), were: experience of mental health problems in the last five years, experience of mental health-related distress in the last six months, resident in England, aged 18+ years, capable of accessing or being supported to access the Internet, able to understand written and spoken English, and capable of providing online informed consent. Participants who reported psychosis experience in the previous five years, defined as being diagnosed with psychosis or having experiences that they or others would call psychotic, were excluded. Experience of

mental health distress in the last six months was evaluated using three items from the Threshold Assessment Grid[24], all as related to current experience of mental health problems.

In order to maximize external validity, since digital health interventions can extend mental health service provision to people not engaged with health services, we recruited participants who had or had not used mental health services to date. Participants were recruited through mental health services by clinical support officers, and publicly through a broad range of community engagement and social media activities led by the central study team[20]. All recruitment advertising and messaging followed ethical principles approved by the ethics committee[25]. All participants continued to receive their usual care, ranging from no treatment through to treatment by secondary or tertiary mental health services.

Clinical outcomes and service usage assessments

The primary outcome was quality of life, assessed through the Manchester Short Assessment (MANSA)[26] at baseline, week 1, week 12, and week 52 (primary endpoint). The MANSA score is the mean of 12 subjective items assessed on a scale from 1 (low quality of life) to 7.

Four clinical secondary outcome measures were performed at baseline and week 52. Hope was assessed using the Herth Hope Index[27], a 12-item measure with sum score ranging from 12 (low hope) to 48. Meaning in life were assessed through the Meaning in Life Questionnaire[28], a 10-item measure producing two mean subscale scores ("presence of meaning" and "search for meaning"), each ranging from 1 (low) to 7. Self-efficacy was evaluated through the Mental Health Confidence Scale[29], a 16-item measure with sum score ranging from 16 (low self-efficacy) to 96. Psychological distress was assessed using the Clinical Outcomes in Routine Evaluation 10 (CORE-10)[30], a 10-item measure capturing relevant aspects of symptomatology, with sum score ranging from 0 (low distress) to 40.

Data for the economic analysis were obtained at baseline and week 52. They consisted of health status data collected through the EQ-5D-5L[31,32], and health service use data obtained through an abridged Client Service Receipt Inventory (CSRI)[33]. Collection forms, ranges and psychometric properties have been previously described[20].

The trial had a target sample of 994, which was selected to provide 90% power to detect a minimal clinically important effect size (Cohen's d) of 0.25 on the mean item score for MANSA, allowing for 40% attrition.

Procedures

Registration and baseline data collection

All recruitment approaches directed potential participants to a website where their eligibility was established through an online self-report questionnaire. If eligible, an electronic participant information sheet was provided, and participants consented by checking a box on an online consent form and then validating an email address. Optionally, a mobile telephone number could be supplied, which was subsequently used by the study team to send messages to encourage engagement with the NEON Intervention.

Participants who confirmed their email address were asked to create an account by providing a password. They completed online forms to collect baseline demographic/clinical items and measures[17] and were then randomized. This process could be completed in multiple sessions to avoid fatigue. Due to concerns about digital exclusion[34], the website was designed to work on most personal computers and mobile devices, including communal computers such as those found in public libraries. A management procedure approved by the Trial Management Group and the Programme Steering Committee enabled auditable decisions to suspend repeat registration accounts.

Randomization

Randomization was through permuted blocks with randomly varying block length (2,4,6), with a 1:1 allocation ratio and no stratification. The automated randomization system embedded in the NEON web application was approved by the supervising trial unit. A randomization list was generated by an independent statistician using the Stata RALLOC package[35,36]. Intervention group users were given immediate NEON Intervention access. Control group users gained access to the NEON Intervention after completing primary endpoint questionnaires.

Follow-up and usage data collection

At week 1 and week 12 after randomization, all participants were prompted by email and on next login to complete web-based questionnaires collecting MANSA responses, and to quantify the number of recovery narratives accessed outside of the NEON Intervention since baseline. At week 52 after randomization, all participants were prompted to complete web-based questionnaires for primary outcome, secondary outcomes, and economic data, and to specify the number of narratives accessed outside of the NEON Intervention since baseline.

Data collection reminders were sent by email, text, and phone call. Due to concerns about primary endpoint questionnaire completion rates, the trial was amended to allow a £20 voucher to be claimed for completion of the 52-week questionnaires[21].

Lateness intervals allowed for questionnaires were 8 days for week 1, 32 days for week 12, and 91 days for week 52. The 52-week lateness interval was adjusted from the protocol (31 days) due to reports that post-pandemic changes such as workplace return were disrupting questionnaire completion. The trial closed to follow-up on September 22, 2022. Data on usage of the NEON Intervention were logged, including details of every narrative request and associated narrative feedback, and interactions with safety features.

National regulation for England indicates that only serious adverse events (SAEs) should be monitored in trials not concerning medicinal products[37]. Possible SAEs were reported through web-based forms for logged-in participants or without login to allow third party reporting. They were also identified retrospectively through hospital use reported on the 52-week CSRI form. Reports detailing possible SAEs were examined and actioned by the Chief Investigator.

The NEON Intervention

The NEON Intervention is a web-based interface providing access to the NEON Collection of recorded recovery narratives. The trial opened with 348 narratives, and (per protocol) narratives were added during the trial period, with 659 narratives available when the final randomized participant reached the primary endpoint. Narratives comprised video, audio, images and text. Every narrative was assessed for inclusion by researchers. All included narratives were characterized using the 77-item researcher-rated Inventory of the Characteristics of Recovery Stories (INCRESE)[38].

The central feature of the NEON Intervention is a homepage providing four narrative access mechanisms, each selected using a button labeled with indicative text. The “Match me to a story” and “Get me a random story” buttons both select a narrative not previously accessed. The former invokes the automated recommender system; the latter uses a random number generator. The “Browse stories” button allows the selection of a narrative using demographic and content categories derived from INCRESE items. The “My stories” button allows return access to narratives previously rated as hope-inspiring or bookmarked by the participant.

After viewing a narrative, participants were asked to rate its immediate impact by responding to up to five validated narrative feedback questions[12]. To maximize response rates, there was one mandatory question on how hopeful the narrative left the participant feeling, with four available responses: “less hopeful than before”; “no change”; “a bit more hopeful”;

“much more hopeful”.

All intervention pages also include buttons to access intervention information (“Welcome”, “About NEON”), to access a guidance page (“I’m upset”), and to rapidly leave the NEON Intervention (“Get me out of here”). Until completing the primary endpoint questionnaires, control group users received access to a simplified homepage excluding narrative access mechanisms.

Before their first access, participants were presented with orienting information and asked to complete an updatable personal profile, where they could identify narrative formats (e.g., text) and content (e.g., self-harm or violence) that they wished to avoid. To familiarize them with the system, participants were shown a first narrative identified empirically as being hope-promoting for feasibility study participants[12], not requiring any content warnings, and conforming to participant format preferences (e.g., a video narrative for participants wishing to avoid text). They were then asked for narrative feedback.

The automated recommender system utilized personal profiles, INCRESE characteristics, and narrative feedback ratings. It was trained with feasibility study usage data[12]. INCRESE characteristics were used to identify narratives similar to those rated positively by the participant (content-based recommendation) using a k-nearest neighbor (kNN) filtering algorithm[39]. Participant profiles were used to identify other similar participant profiles, and then to identify narratives rated positively by these latter participants (collaborative recommendation) using singular value decomposition (SVD) and SVD++ filtering algorithms[39]. The narrative with the highest estimated rating was selected from a combined list.

We used multiple approaches to encourage engagement, whilst considering the need of enabling participants to self-manage engagement. From trial start, engagement messages were sent to participants with intervention access, both by email and text message. Some messages linked directly to exemplar narratives. During the trial, we added functionality to encourage engagement. This consisted of anonymized participant testimonials, “badges” (graphical symbols received on meeting thresholds such as 10 narrative requests), and a system for capturing personal reflections on impactful narratives.

Trial analyses

The economic analysis was conducted in Stata version 16.1 (StataCorp LLC). All other analyses were conducted in R version 4.1.2 (R Foundation, 64-bit implementation). The statistical significance level was two-sided 5%. Analysis used a prospectively-modified intention-to-treat sample which excluded accounts suspended due to repeat registration[18].

Clinical outcomes analysis

The analysis of primary and secondary outcomes used a linear regression model of outcome at week 52 adjusting for baseline. Multiple imputation was used to impute all missing baseline and clinical outcomes using the MI package[40], assuming that data were "missing at random" (MAR). Fifty datasets were generated, and parameters from each individual analysis were combined using Rubin's rules.

To examine differential effects on clinical effectiveness, the primary analysis was repeated to include an interaction term between treatment and three demographic items: gender, ethnicity, and (for prior health service usage) use of specialist care mental health services. Baseline clinical outcomes data collected during times of national lockdown were compared with those collected outside of lockdown, using t-tests. With MANSA data collected at week 1, week 12 and week 52, a mixed effect model using random effects for intercept parameters and days of measurement from baseline was fitted, and adopted to examine interactions with periods coded as within national lockdown. Both analyses used dates documented in the statistical analysis plan[18].

We examined the sensitivity of our findings to protocol deviations by conducting a complete case analysis as well as per-protocol analyses excluding repeat registration cases where the intervention group account was retained; randomized in error participants; participants who completed week-52 outcome assessments late; and control group participants who obtained NEON Intervention access due to a technology error. We examined the sensitivity of our findings to missingness by conducting a complete case analysis with significant predictors for missingness added as covariates, and multiple imputation using a pattern mixture model to assess robustness with plausible departures from MAR[41].

Health economic analysis

A within-trial cost-effectiveness analysis compared the cost and quality-adjusted life years (QALYs) gained for both study arms from the perspective of the National Health Service (NHS) in England. Downstream health care resource use was calculated for both arms using CSRI data combined with UK-based unit costs. EQ-5D-5L responses collected at baseline and at week 52 were converted to EQ-5D-3L utility values (UK tariff)[42], as required by the National Institute for Health and Care Excellence (NICE)[43], using an established mapping method[44]. QALYs were calculated from per-participant utility values, assuming a linear relationship between the time points[45]. Mean total cost (log-link and Gamma family) and QALYs (identity-link and Gaussian family) were estimated for each arm using generalized linear models and recycled predictions adjusting for trial allocation and baseline characteristics (age, gender,

MANSA total score), baseline EQ-5D-3L utility, and baseline cost (cost regression only)[45]. Multiple imputation was used for missing data (assumption: MAR).

The main outcome was the incremental cost-effectiveness ratio (ICER), calculated as the ratio of incremental costs to incremental QALYs. Uncertainty was handled by bootstrapping with 2,000 replications. Cost-effectiveness was determined against thresholds of £20,000 and £30,000 per QALY gained[43]. Sensitivity analyses were performed to assess robustness of base-case results, incorporating a range of assumptions on intervention delivery cost, QALY derivation and health service resource cost. In one sensitivity analysis, missing data were imputed using a pattern mixture model to assess robustness with plausible departures from MAR[41]. In a pre-planned subgroup analysis, an ICER was calculated for lifetime specialist care mental health service users only.

RESULTS

Participant flow

Trial recruitment took place between March 9, 2020 and March 26, 2021. During this period, a total of 2,096 people were eligible for the trial, of whom 1,123 (54%) completed the registration process. The most common reasons for non-participation were not requesting a consent form after receiving the participant information sheet (N=835), and not validating an email address after completing the consent form (N=138). One hundred repeat registration accounts were suspended. The remaining 1,023 accounts formed the modified intent-to-treat sample. There were more participants in the control (N=516) than in the intervention (N=507) arm, due to imbalance in account suspensions. Seven control group participants received early access to the NEON Intervention due to a technology error. The error was rectified, and NEON Intervention access was suspended until follow-up at week 52 for these participants.

Of the 507 intervention arm participants, 473 (82.1%) accessed at least one narrative and are identified as having received the intervention. Withdrawals were 17 in the intervention and 4 in the control arm. Missing quality of life data at week 52 were 273 (54.0%) in the intervention and 185 (35.9%) in the control arm. The participant flow is shown in Figure 1.

Baseline demographic and clinical characteristics

Baseline demographic and clinical characteristics were similar across treatment groups (see Table 1). All regions in England and all levels of educational attainment were represented. Mean age was 38.4±13.6 years. Of the 1,023 participants, 910 (89.9%) were White, 827

(80.8%) were White British, 811 (79.3%) were female, 794 (77.6%) lived with others, 586 (57.3%) were employed, and 272 (26.6%) were unemployed. The most common primary mental health problems experienced in the month before registration were mood and/or anxiety disorders (N=626, 61.2%) and stress-related disorders (N=152, 14.9%). Specialist care mental health services had been accessed by 614 participants (60.0%) and primary care mental health services by 949 participants (92.8%).

Baseline data collected through assessment instruments were similar across treatment groups (see Table 2). Baseline MANSA data were provided by 444 participants (39.1%) during a national lockdown period, and by 579 participants (60.9%) outside of a national lockdown period. There was no evidence that national lockdown influenced baseline quality of life (difference: 0.00, 95% CI: –0.11 to 0.12, p=0.94) or any secondary outcomes at baseline.

Effectiveness data

All participants in the modified intent-to-treat sample (N=1,023) were included in the primary analysis.

At week 52, we found a significant baseline-adjusted difference in the MANSA score between the intervention and control groups (0.13, 95% CI: 0.01-0.26, p=0.041), indicating that the NEON Intervention increased quality of life. There are 12 items in the MANSA; hence this equates to a mean change of 1.56 scale points per participant. This finding was sensitive to small departures from MAR, since it became insignificant if people in the intervention arm with missing data had a reduction of more than 1% in their MANSA score compared with individuals who had observed data. There were no significant baseline-adjusted differences in the MANSA score at week 12 (0.06, 95% CI: –0.05 to 0.16, p=0.30) and week 1 (0.05, 95% CI: –0.04 to 0.13, p=0.26) (see Table 3).

We also found a significant baseline-adjusted difference in meaning in life (presence of meaning subscale) at week 52 (0.22, 95% CI: 0.05-0.40, p=0.014), indicating that the NEON Intervention increased the presence of meaning in life. This equates to a mean change of 1.1 scale points per participant. There were no significant differences in other secondary outcomes (see Table 3).

The primary analysis was repeated to examine interaction effects between clinical effectiveness and three demographic items: gender, ethnicity, and (for prior health service usage) use of specialist care mental health services. For CORE-10, there was evidence of differential effectiveness by gender (p=0.004). For meaning in life (presence of meaning subscale), there was evidence of differential effectiveness by ethnicity (p=0.02). There was no evidence for differential effectiveness by lifetime specialist service use (see Table 4).

To collect evidence for the nature of the interaction, we calculated baseline-adjusted

differences for those pairings with a significant differential effect. For gender, we found a significant difference in CORE-10 score when comparing intervention arm with control arm females (–1.74, 95% CI: –2.98 to –0.49, p=0.006), providing evidence that the NEON Intervention reduced psychological distress for females. There was no significant change when comparing intervention arm to control arm males (2.55, 95% CI: –0.43 to 5.53, p=0.09).

For ethnicity, we found a significant increase in meaning in life (presence of meaning subscale) when comparing White British participants in the intervention vs. control arms (0.34, 95% CI: 0.12-0.56, p=0.003), but no significant change for minority ethnic participants (–0.30, 95% CI: –0.89 to 0.28, p=0.30).

When we examined the sensitivity of our findings to protocol deviations by conducting a complete case analysis (N=565), we found an identical baseline-adjusted MANSA difference at week 52 for all protocol deviations examined individually and collectively. Hence we conclude that our MANSA findings are not sensitive to protocol deviations. When we adjusted our complete case analysis for predictors of missingness, the baseline-adjusted difference in meaning in life (presence of meaning subscale) was lower, but still positive and significant (0.22, 95% CI: 0.0057-0.42, p=0.04). In our mixed effects model, there were no evidence that national lockdown influenced MANSA data collected at any follow-up.

Cost-effectiveness

Total cost data were available for 191 (37.7%) intervention arm and 291 (56.4%) control arm participants. Total QALY data were available for 187 (36.9%) intervention arm and 282 (54.7%) control arm participants. All analyses hereafter used multiple imputation if data were missing.

In the adjusted base-case analysis, total mean cost per participant at week 52 was £1,960 for the intervention arm and £1,782 for the control arm. Therefore, the NEON Intervention increased costs by £178 per participant (95% credible interval: –£154 to £455). Total mean QALYs at week 52 were 0.5770 for the intervention arm and 0.5628 for the control arm. Therefore, the NEON Intervention increased QALYs by 0.0142 per participant (95% credible interval: 0.0059 to 0.0226) (see Table 5).

The ICER was £12,526 per QALY gained, which was less than the selected cost-effectiveness thresholds (£20,000; £30,000), indicating that the NEON Intervention would be a cost-effective use of health service resources (see Table 5).

The ICER was lower than £30,000 in all but one sensitivity analysis (cost of intervention, worst case). When the costs of delivering the NEON Intervention were omitted, the incremental cost between intervention and control was –£170 (95% credible interval: –£507 to £108), indicating that intervention arm membership reduced non-NEON health service resource use.

Figure 2 reports the cost-effectiveness acceptability curve illustrating probability of cost-effectiveness at different threshold values. The probabilities of cost-effectiveness were 71.2% (£20,000 per QALY gained) and 88.2% (£30,000 per QALY gained).

The base-case analysis assumed that all data were missing at random. Sensitivity analysis indicated that, if data were not missing at random, the NEON Intervention would no longer be cost-effective against the £30,000 per QALY threshold if people in the intervention arm with missing data have a reduction of more than 2.3% in their total QALYs gained, compared with individuals who have observed data.

Service usage

We conducted a subgroup analysis including all participants who had used specialist care mental health services at baseline. For this subgroup, the per-participant incremental cost was negative between intervention and control (–£98, 95% credible interval: –£606 to £309), and there was a per-participant QALY gain (0.0165, 95% credible interval: 0.0057 to 0.0273). Hence, the NEON Intervention was classified as dominating usual care for this subgroup, i.e. both reducing costs and improving QALYs.

Intervention usage

A total of 10 (1%) intervention arm participants requested technical support to access the intervention. For those intervention arm participants who received the intervention (i.e., accessed at least one narrative), the median number of narrative requests was 3 (interquartile range: 1-7, minimum: 1, maximum: 107). In total, 327 (69%) of these participants provided at least one narrative feedback item. Of the 2,908 intervention arm narrative requests, 1,559 (54%) received a feedback item on hope. Of these, 168 (11%) indicated that the participant was less hopeful than before accessing the narrative, 544 (35%) that he/she was a bit more hopeful, 175 (11%) that he/she was much more hopeful, and 672 (43%) that there was no change.

Non-NEON narrative usage

Recovery narratives are publicly available on a substantial scale. So, we used a questionnaire to collect information on access to recovery narratives not provided through the NEON Intervention. At week 52, 316 (31%) participants had accessed at least one narrative outside of the NEON Intervention since baseline, comprising 172 (33%) control group and 144 (29%) intervention group participants. Those accessing more narratives through the NEON

Intervention also accessed more narratives through other non-NEON routes (Kruskal-Wallis test: $p<0.001$ for each follow-up time).

Safety analysis

There was one SAE related to trial participation in the intervention arm, which was associated with a recovery story triggering substantial distress. This was an expected harm detailed in the NEON Impact model and on the participant information sheet. The participant discontinued use of the NEON Intervention. There were no related SAEs in the control arm.

DISCUSSION

This study demonstrates that the NEON Intervention is effective in increasing quality of life for people experiencing non-psychotic mental health problems, as assessed after 52 weeks of access. Our intention-to-treat analysis found a significant baseline-adjusted difference of 0.13 (95% CI: 0.01-0.26, $p=0.041$) in the MANSA score between the intervention and control groups, corresponding to a mean change of 1.56 scale points per participant.

It proved to be feasible for most participants to use the NEON Intervention independently of the study team, with only a very small number of users (1%) requiring technical support to access the platform. This capacity for independent usage of the intervention suggests the feasibility of scaling it up. Hence, the relatively small increase in quality of life at the individual level is likely to produce a substantial mental health impact if the NEON Intervention is provided at population level.

Our study also demonstrates that the NEON Intervention is cost-effective from the perspective of health commissioning. The ICER was £12,526 per QALY gained, which was less than the selected cost-effectiveness thresholds (£20,000; £30,000). For the subgroup of participants who had previously used specialist care mental health services, the per-participant incremental cost was negative between intervention and control, and there was a per-participant QALY gain, so that the intervention was classified as dominating usual care, i.e. both reducing costs and improving QALYs. The intervention is likely to be even more cost-effective in a population-level implementation scenario, because the resources required to deliver it in practice will be mostly quasi-fixed costs, allowing the cost components to be apportioned across increasing numbers of users.

Whilst assembling our narrative collection for use in the trial took a substantial effort from the study team, several participants decided, in turn, to offer their narrative to the NEON Collection, inspired by their trial experiences. Therefore, population-scale deployment of the

intervention may lead to a virtuous circle of narrative donation, with each donation increasing the diversity of mental health experiences present in the collection. This is important, since the NEON Impact model positions connection with a narrative as a mechanism, and the likelihood of connection is enhanced by greater narrative diversity in the collection[47].

The potential for easy scalability is a critically important characteristic of the NEON Intervention, in the light of the ongoing mental health treatment gap[48]. A survey of psychiatric leaders in 57 countries suggested that the increased delivery of treatment in non-psychiatric settings and an increased availability of a range of interventions are both important strategies for supporting help-seeking around mental health whilst reducing the treatment gap[49]. The NEON Intervention only requires a computer or smartphone and Internet access, and hence it may have a role to play in the delivery of these strategies, particularly as the rapidly increasing availability of mobile and networking technologies will make the delivery of digital health interventions ever more practical in lowest resource settings[50]. Modifications of the intervention to enable success in these settings might be considered, such as enabling accessibility on low-specification (and hence low-cost) phones or networks. Different cultures can influence adoption of digital health interventions[51] and hence cultural adaptation of the NEON Intervention should be considered to enhance adoption[52].

Our study had some limitations. We recruited a convenience sample, which was largely female. Recorded recovery narratives are widely available to the public, and hence access by the control group was possible and did occur, though our findings demonstrate that greater NEON Intervention narrative access was associated with greater public recovery narrative access, suggesting that NEON Intervention use led to public recovery narrative use. Some data were imputed, and our findings are sensitive to our missing data assumptions. Our recruitment period was during the COVID-19 pandemic, and the limitations imposed by this period may have increased the influence of digital exclusion, such as ability to access public computers. Most of our follow-up period may have been influenced by these factors as well.

There was little evidence for safety concerns from our trial, as the one related SAE that was reported was resolved through discontinuation of the intervention. However, our approach to safety data collection was limited, as our national regulator only allowed monitoring of SAEs, and hence we did not monitor for adverse events not classified as serious, and our approach to safety monitoring required active report of possible SAEs. Since important safety concerns can be identified through the inspection of non-serious or not actively reported adverse events[53], we cannot draw a definitive conclusion on intervention safety from our trial, and ongoing monitoring of safety is indicated with more widespread availability.

From our findings, we conclude that the NEON Intervention is a low-intensity self-management intervention which has demonstrated effectiveness and cost-effectiveness for people with non-psychotic mental health problems in an England-wide trial. Implementation at

a population level is indicated, with appropriate monitoring for safety of usage. Evaluation of integration of the intervention in mental health services as an adjunct to usual clinical practice can be recommended. The next steps include refinement for use in other linguistic and cultural settings, and extension to other clinical populations, and we are actively supporting a range of international follow-on studies.

A future integration of these initiatives into a single multi-language and multi-disorder online intervention would be an innovative approach to addressing the multimorbidity challenges of increasingly diverse national populations.

ACKNOWLEDGEMENTS

This study was funded by the UK National Institute for Health and Care Research (NIHR) (RP-PG-0615-20016). M. Slade and S. Rennick-Egglestone are supported by the NIHR Nottingham Biomedical Research Centre (NIHR203310). G. Thornicroft is supported by the NIHR Applied Research Collaboration South London at King's College Hospital NHS Foundation Trust, and by the UK Medical Research Council. The views expressed here are those of the authors and not necessarily those of the NIHR or the UK Department of Health and Social Care. The authors would like to thank T. Hamburg for quality-checking statistical elements of trial analyses. The NEON Study Group comprises C. Bond, S. Booth, S. Bradstreet, S. Brown, F. Callard, A. Charles, P. Cuijpers, L. Davidson, P. Davis, R. Elliott, M. Farkas, D. Franklin, S.P. Gavan, S. Gillard, T. Glover, A. Grundy, L. Hare-Duke, J. Harrison, A. Hui, J. Keppens, D. King, J. Llewellyn-Beardsley, L. Matthews, R. McGranahan, G. Morgan, F. Ng, H. Nudds, L. Paterson, K. Pollock, S. Pomberth, S. Priebe, D. Quadri, A. Ramsay, S. Rennick-Egglestone, K. Rimmer, C. Robinson, D. Robotham, J. Roe, E. Slade, M. Slade, M. Smuk, G. Thornicroft, L. van der Krieke, R. Walcott, L. Wells and C. Yeo. M. Slade and S. Rennick-Egglestone contributed equally as first authors, and F. Ng and J. Llewellyn-Beardsley contributed equally as last authors.

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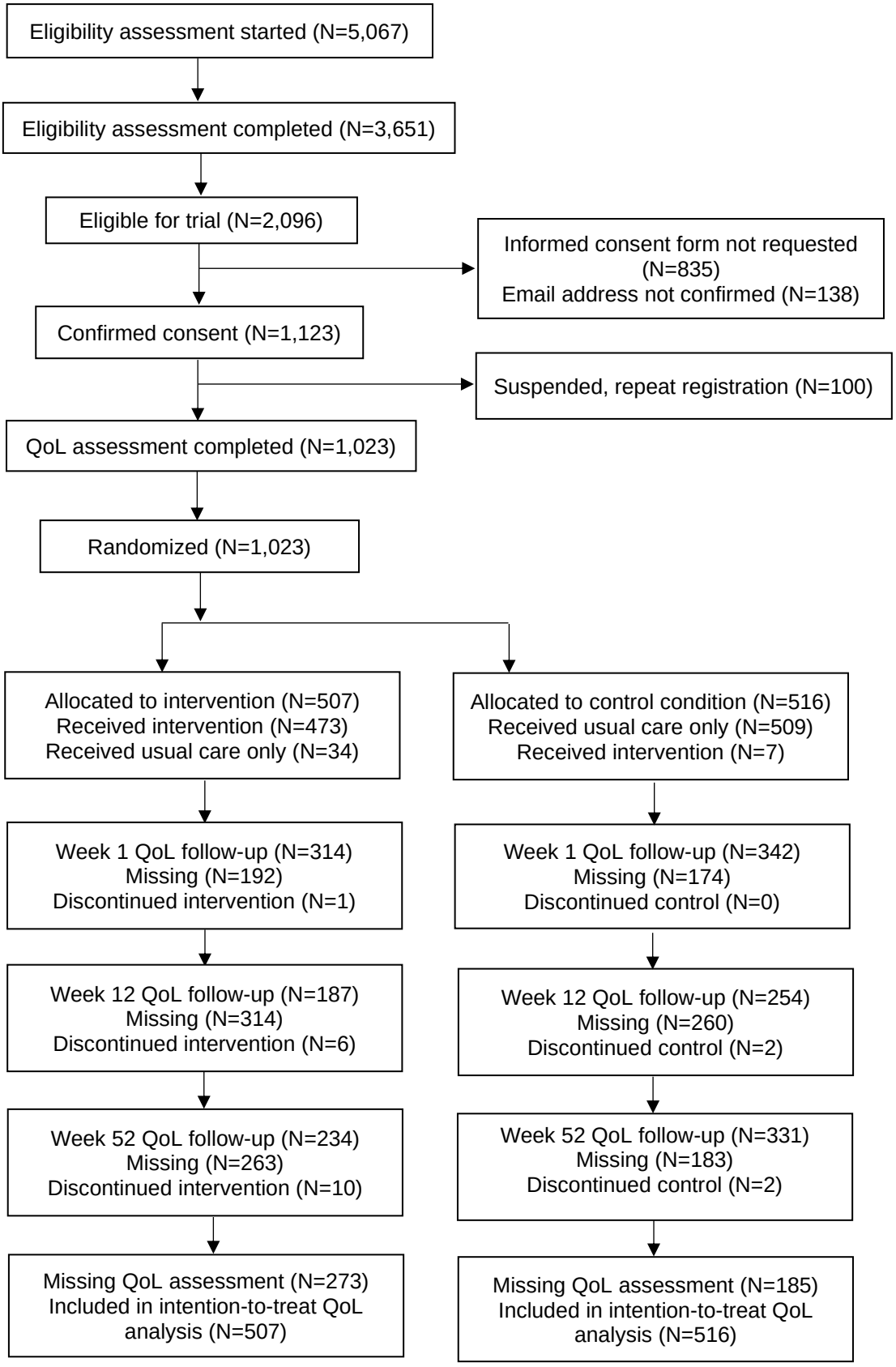

Figure 1 CONSORT diagram. QoL – quality of life

Table 1 Baseline demographic and clinical characteristics of participants

	Intervention (N=507)	Control (N=516)	Total (N=1,023)
Gender, N (%)			
Female	387 (76.3)	424 (82.2)	811 (79.3)
Male	103 (20.3)	81 (15.7)	184 (18.0)
Other	11 (2.2)	7 (1.4)	18 (1.8)
Age (years), mean±SD	38.6±13.5	38.2±13.6	38.4±13.6
Ethnicity, N (%)			
White	441 (87.0)	469 (90.9)	910 (89.9)
White British	391 (77.1)	436 (84.5)	827 (80.8)
Mixed/Multiple ethnic background	19 (0.04)	8 (0.02)	27 (0.03)
Asian	30 (0.06)	17 (0.03)	47 (0.05)
Black/African/Caribbean	10 (0.02)	14 (0.03)	24 (0.02)
Region of current residence, N (%)			
East of England	31 (6.1)	30 (5.8)	61 (6.0)
London	111 (21.9)	99 (19.2)	210 (20.5)
Midlands	104 (20.5)	99 (19.2)	203 (19.8)
North East and Yorkshire	50 (9.9)	52 (10.1)	102 (10.0)
North West	45 (8.9)	53 (10.3)	98 (9.6)
South East	101 (19.9)	113 (21.9)	214 (20.9)
South West	59 (11.6)	66 (12.8)	125 (12.2)
Education, highest qualification, N (%)			
No qualification	18 (3.6)	12 (2.3)	30 (2.9)
Secondary education	55 (10.8)	61 (11.8)	116 (11.3)
Vocational qualification	161 (31.8)	166 (32.2)	327 (32.0)
Degree level qualification	165 (32.5)	184 (35.7)	349 (34.1)
Higher degree level qualification	102 (20.1)	89 (17.2)	191 (18.7)
Mental health service use, N (%)			
Ever used primary care mental health services	470 (92.7)	479 (92.8)	949 (92.8)
Ever used specialist care mental health services	303 (59.8)	311 (60.3)	614 (60.0)
Main mental health problem in the last month, N (%)			
Mood and/or anxiety disorders	314 (61.9)	312 (60.5)	626 (61.2)
Stress-related disorders	72 (14.2)	80 (15.5)	152 (14.9)
Personality disorders	66 (13.0)	57 (11.0)	123 (12.0)
Eating disorders	18 (3.6)	27 (5.2)	45 (4.4)
Neurodevelopmental disorders	–	–	12 (1.2)
Substance-related disorders	–	–	8 (0.8)
Other (less than 5 participants) or unspecified	37 (7.3)	40 (7.8)	57 (5.5)
Residential status, N (%)			
Alone	123 (24.3)	106 (20.5)	229 (22.4)
With others	384 (75.7)	410 (79.5)	794 (77.6)
Occupation, N (%)			
Employed	280 (55.2)	306 (59.3)	586 (57.3)

Sheltered employment	–	–	6 (0.6)
Training and education	51 (10.1)	55 (10.7)	106 (10.4)
Unemployed	144 (28.4)	128 (24.8)	272 (26.6)
Retired	30 (5.9)	23 (4.5)	53 (5.2)

Cells with less than 5 participants appear with a "–" sign. The total for some items does not correspond to the N for the overall sample due to some missing data.

Table 2 Results of baseline assessments

	Intervention (N=507)	Control (N=516)	Total (N=1,023)
Manchester Short Assessment (MANSA) score, mean±SD	3.8 (0.9)	3.8 (0.9)	3.8 (0.9)
Missing, N (%)	0 (0)	0 (0)	0 (0)
Clinical Outcomes in Routine Evaluation 10 (CORE-10) score, mean±SD	21.7 (7.2)	21.6 (7.3)	21.6 (7.3)
Missing, N (%)	9 (1.8)	10 (1.9)	19 (1.9)
Herth Hope Index score, mean±SD	28.9 (6.6)	28.9 (7.1)	28.9 (6.9)
Missing, N (%)	10 (2.0)	10 (1.9)	20 (2.0)
Mental Health Confidence Scale, mean±SD	51.7 (13.8)	51.5 (14.5)	51.6 (14.2)
Missing, N (%)	9 (1.8)	11 (2.1)	20 (2.0)
Meaning in Life Questionnaire, "presence of meaning" subscale score, mean±SD	3.4 (1.4)	3.4 (1.5)	3.4 (1.5)
Meaning in Life Questionnaire, "search for meaning" subscale score, mean±SD	4.7 (1.5)	4.7 (1.4)	4.7 (1.4)
Missing (for entire questionnaire), N (%)	10 (2.0)	12 (2.3)	22 (2.2)
EQ5D-3L score, median (interquartile range)	0.6 (0.4-0.8)	0.6 (0.4-0.7)	0.6 (0.4-0.8)
Missing, N (%)	11 (2.2)	12 (2.3)	23 (2.2)

Table 3 Primary analysis of effectiveness of intervention vs. usual care

	Baseline-adjusted difference (95% CI)	**p**
Manchester Short Assessment (MANSA) score (week 52)	0.13 (0.01-0.26)	**0.041**
MANSA score (week 12)	0.06 (–0.05 to 0.16)	0.30
MANSA score (week 1)	0.05 (–0.04 to 0.13)	0.26
Clinical Outcomes in Routine Evaluation 10 (CORE-10) score (week 52)	–0.72 (–1.74 to 2.41)	0.17
Herth Hope Index score (week 52)	0.45 (–0.56 to 1.46)	0.39
Mental Health Confidence Scale score (week 52)	1.40 (–0.83 to 3.63)	0.22
Meaning in Life Questionnaire, "presence of meaning" subscale score (week 52)	0.22 (0.05-0.40)	**0.014**
Meaning in Life Questionnaire, "search for meaning" subscale score (week 52)	0.05 (–0.13 to 0.23)	0.59

Significant findings are highlighted in bold

Table 4 Interaction effects between clinical effectiveness (at week 52) and some pre-identified variables (p values)

	Lifetime specialist services use	Gender	Ethnicity
Manchester Short Assessment (MANSA) score	0.10	0.45	0.80
Clinical Outcomes in Routine Evaluation 10 (CORE-10) score	0.25	**0.004**	0.73
Herth Hope Index score	0.56	0.89	0.09
Mental Health Confidence Scale score	0.31	0.27	0.72
Meaning in Life Questionnaire, "presence of meaning" subscale score	0.70	0.96	**0.02**
Meaning in Life Questionnaire, "search for meaning" subscale score	0.28	0.39	0.99

Significant findings are highlighted in bold

Table 5 Base-case economic analyses and sensitivity analyses

	Cost			QALYs			ICER
	Intervention	**Control**	**Incremental**	**Intervention**	**Control**	**Incremental**	
Base-case analyses							
Adjusted base-case analysis	£1,960	£1,782	£178 (–£154 to £455)	0.5770	0.5628	0.0142 (0.0059 to 0.0226)	**£12,526**
Unadjusted base-case analysis	£2,373	£3,472	-£1,099 (–£2,494 to £19)	0.5652	0.5744	–0.0091 (–0.0369 to 0.0196)	£120,547
Sensitivity analyses							
Cost of intervention, best case	£1,895	£1,774	£122 (–£205 to £399)	0.5781	0.5630	0.0151 (0.0069 to 0.0234)	**£8,057**
Cost of intervention, worst case	£2,232	£1,740	£492 (£155 to £770)	0.5784	0.5633	0.0151 (0.0068 to 0.0233)	£32,582
Cost of intervention, no fixed cost	£1,830	£1,802	£28 (–£301 to £306)	0.5771	0.5637	0.0134 (0.0050 to 0.0215)	**£2,102**
Cost of intervention, zero cost	£1,629	£1,799	–£170 (–£507 to £108)	0.5774	0.5626	0.0148 (0.0063 to 0.0233)	**Dominant**
QALY generalized linear model, Poisson family	£1,974	£1,780	£194 (–£136 to £471)	0.5793	0.5619	0.0175 (0.0086 to 0.0258)	**£11,123**
Cost of non-mental health inpatient stay, per day payment	£1,954	£1,745	£209 (–£126 to £489)	0.5787	0.5640	0.0147 (0.0062 to 0.0228)	**£14,253**
Cost of non-mental health inpatient stay, zero cost	£1,863	£1,595	£268 (–£53 to £531)	0.5767	0.5637	0.0130 (0.0049 to 0.0213)	**£20,635**
Multiple imputation, omitting baseline variables	£1,735	£1,759	–£24 (–£377 to £264)	0.5703	0.5638	0.0066 (–0.0020 to 0.0150)	**Dominant**
Complete case analysis	£1,758	£1,706	£52 (–£574 to £609)	0.5753	0.5711	0.0042 (–0.0122 to 0.0210)	**£12,573**

Credible intervals for incremental outcomes are reported in parentheses. QALY – quality-adjusted life year, ICER – incremental cost-effectiveness ratio. ICERs indicating cost-effectiveness at a threshold of £30,000 are highlighted in bold. “Dominant” indicates that the ICER is negative.

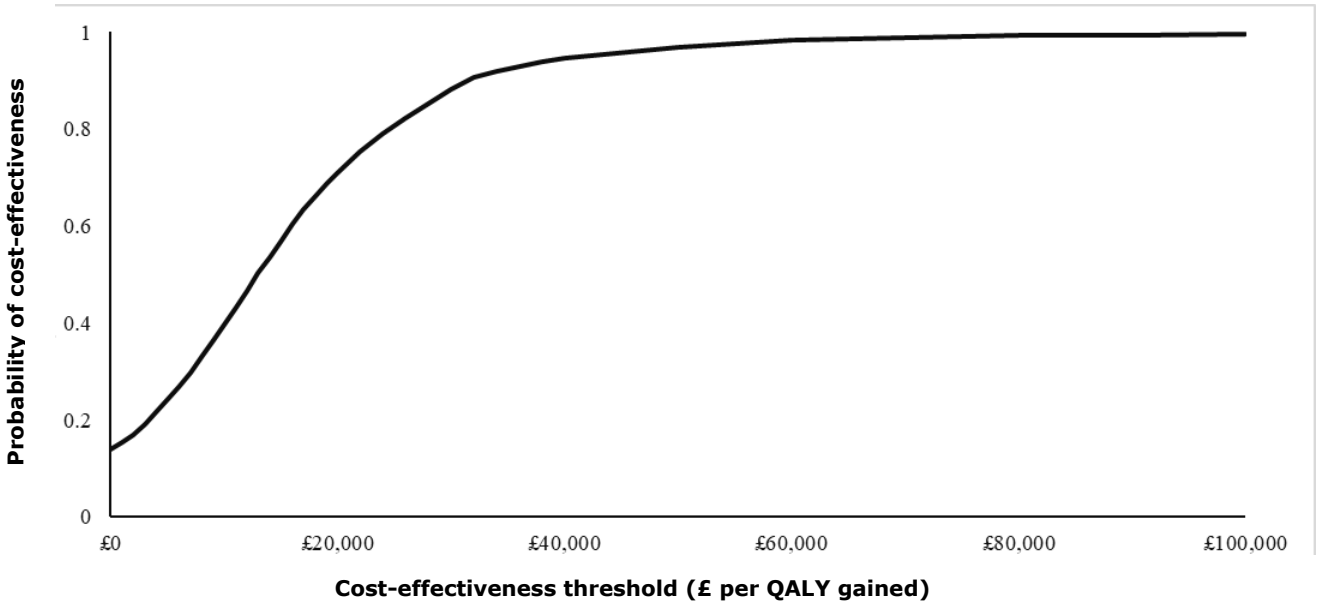

Figure 2 Cost-effectiveness acceptability curve (adjusted base-case analysis). QALY – Quality-adjusted life year