Branching Out Economic Study Extension

Final Report to Forestry Commission Scotland

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Final Report

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Contents

Acknowledgements

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1 Executive summary

Background

A previous study reported on the report on the Health-related Quality of Life (HRQoL) benefits from participation in Forestry Commission Scotland's Branching Out programme. Analysis of the pre- and post-programme questionnaires demonstrated benefits in the 2011/12 period measured in Quality Adjusted Life Years (QALYs). The intervention was cost-effective when assessed against NICE guidelines. However, the QALY improvements were not statistically significant.

It was decided to continue recording pre- and post-programme health states in 2014/15 using the same SF-12 questionnaire in order to increase the number of observations for analysis. This meant that two cohorts (2011/12 and 2014/15)[1] were now available for exploring benefits from the Branching Out programme.

Objectives of the study

The aim of the current study was to obtain additional client QALY data from questionnaires applied in the 2014/15 period in order to:

- ❑ Increase the number of client records from which QALY changes could be derived;
- ❑ Translate the SF-12 scores for the extended period of observation into SF-6D scores from which a single QALY score could be obtained for each respondent;
- ❑ Assess whether a larger sample would deliver statistically significant effects for the intervention; and
- ❑ Use the extended dataset as the basis for new estimates of cost-effectiveness.

Method

Over time there have been changes in the referring organisations and in the bodies which deliver the programme. However the delivery of the programme is standardised as far as possible by all delivery staff undergoing a uniform training programme.

We examined the two datasets (2011/12 and 2014/15) independently and in combination. The same method of analysis was used as previously. The SF-12 HRQoL questionnaire was used, and from this six SF-6D dimensions were derived (Brazier et al 2004). In turn, a single Quality of Life Years (QALY) score could then be calculated for the SF-6D dimensions. Participants were asked to complete questionnaires pre- and immediately post- programme and then 3 months post-programme.

Participation

The 2014/15 database recorded 359 participants of whom 305 attended at least one session. The number completing both pre- and post-programme questionnaires was 102, a 33% response rate.

QALY changes

The main analysis was of the change in QALYs and SF-6D dimensions from pre-programme to immediate post-programme. The 2014/15 dataset showed small but significant improvements in SF-mental, SF-role and SF-vital for those participants who completed pre- and post-programme questionnaires. The QALY benefits (mean +0.000347) were not as great as those observed in 2011/12 (+0.04955). The pooled QALY gain for 2011-15 was +0.00269[2]. The

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[1] Results from a previous 2007/08 study were omitted.   They were no longer considered relevant due to changes in the delivery of the programme since that time,

[2] Although results are given for the whole period 2007-2015 we have discounted the earlier observations since these are dated and do not reflect changes in the programme over time.

evidence continues to support the conclusion that Branching Out improves mental health, social participation and general vitality. The lack of statistical significance for the 2014/15 data (and in the pooled dataset (2011-15)) may reflect the much greater proportion of missing data in the 2014/15 dataset than in the earlier data sets.

Duration of effects
It is important to discover whether the effects of Branching Out are sustained when the course ends. However, there was a paucity of 3 month post-programme records (48) and these showed no evidence that benefits were maintained. It would require much more complete records to analyse this aspect satisfactorily.

Impact of other factors
We analysed for the effect of other variables on QALY change (pre-programme compared with immediate post-programme) including gender, age, client type (by referring agency), number of weeks attended pre-programme QALY and SF-6D dimension scores. The analysis revealed positive effects of pre-programme SF-mental and SF-vital scores on QALY change.

The pre-course mental health state and vitality of participants are important determinants of the gain in quality of life during the course. Those with poor states as measured by these SF-12 dimensions benefit most. If these states could be related to the type and severity of the psychotic disorder suffered by patients there may be more scope for identifying those for whom Branching Out offers the greatest benefit.

Costs and cost-effectiveness
The financial cost per participant of continuing to operate Branching Out was estimated at £392 per participant in 2014/15. Based on the pooled QALY change estimated from the 2011-15 records the cost per QALY in 2014/15 was £17.3K. The programme remained cost-effective over its 12 week intervention as assessed against the NICE £30K per QALY benchmark. This assumes the benefits are retained for a year. Due to the small number of records we were unable to be definitive on the duration of QALY benefits. If benefits lapse over time this suggests a sequence of intervention measures is needed in order to build on the shorter term benefits.

Retention rates
When compared to a number of other community-based metal health interventions Branching Out has generally higher initial attendance and retention rates (as measured by >4 attendances). High retention rates are an indicator of satisfaction with the intervention on the part of those participating.

Conclusions
In summary, the main conclusions from this extension of the original study are:

- ❑ The programme delivers benefits to participants and these are principally for participants with higher (worse) Mental Health and Vitality scores at entry to the programme. Participants in the 2011-12 cohort had significantly worse initial SF-6D scores for Mental Health and Vitality, and showed greater QALY improvement than participants in the 2014-15 cohort.
- ❑ There were differences between the QALY gains in the cohorts studied (2011/12 and 20014/15). This may be due to the differences in SF-6D Mental Health and Vitality between the cohorts on entry to the programme. .
- ❑ Greater discretion in client selection could in principle be used to increase the cost-effectiveness of Branching Out. It is not clear how this might be achieved in practice but we suggest that any options for better matching what the programme offers to the needs of clients is worth exploring.
- ❑ Programme delivery costs per participant were lower in 2014/15 than in 2011/12 but the QALY gain by participants was also lower.

❑ The programme cost-effectiveness in 2014/15 was £17.3K per QALY, based on the 2011-15 mean QALY change attributed to the programme. The evidence on the duration of the benefit delivered by participation was unclear. Were the benefit to be maintained for a year then the intervention would be judged as cost-effective when assessed against the NICE guideline of £30,000 per QALY. Comparable therapies showed a wide range of costs per QALY with Branching Out falling within the overall range.

❑ Initial attendance and retention rates (>4 sessions completed) were higher in the Branching Out programme than in the comparators. High retention rates are an indicator of satisfaction with the intervention on the part of those participating.

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2 Introduction

2.1 The Branching Out Programme

The Branching Out Programme (BOP)[3] is run by Forestry Commission Scotland (FCS) and aims to improve the Health-related Quality of Life (HRQoL) of adults experiencing severe and enduring mental health problems. It is an adjunct treatment for those in secondary and tertiary care. Details of the programme are given in a report to Forestry Commission Scotland made in 2013[4]. The programme operates within the framework and objectives set out in the Scottish government's Mental Health Strategy 2012-15[5].

2.2 Results from the previous study

A previous economic analysis of the costs and benefits of the Branching Out programme estimated the Quality Adjusted Life Year (QALY) benefits delivered by the programme in 2007/08 and 2011/12. The 2007/08 dataset was collected by Wilson (2009) whereas the 2011/12 dataset was derived from questionnaires implemented as part of a new study.

The analysis revealed differences between the two datasets, in that the 2011/12 participants had a poorer pre-programme health status than those in 2007/08 and the health improvements during the course were greater. The reason for these differences was unclear although evolution in the format of programme delivery and more appropriate matching of participants to the programme may have been factors. Given these differences it was concluded that the programme effectiveness was best estimated from the 2011/12 dataset.

The mean QALY score for the improvement attributable to Branching Out in 2011/12 was 0.0495, with a standard deviation of 0.1045 (n=73). Cost-effectiveness, measured as the mean QALY improvement per person divided by the cost per person of programme delivery, was estimated as £8.6-11.5K per QALY for all participants (Table 2.1). Those participants completing the pre- and post-programme questionnaires attended more sessions (than the mean for all participants) and the cost per QALY was lower at £8,600 (Table 2.1). Both the £8,600 and £11,480 per QALY are well below the NICE guidelines for cost-effective intervention of £30,000 per QALY.

Table 2.1: QALY change and cost-effectiveness

	Mean QALY change	Cost per QALY at £426 per user per year(£)
Those completing pre- and post-questionnaires (n=73), attending an average of 9.55 sessions	0.0495	£8,600
All participants (n=335), attending 7.16 sessions	0.0371	£11,480

One problem with the previous analysis was the limited number of observations which meant that many of the health differences pre- and post-programme were not

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[3] For details of the programme see http://www.forestry.gov.uk/branchingout.
[4] CJC Consulting (2013). Branching Out Economic Study. Report to Forestry Commission Scotland.
[5] http://www.gov.scot/Topics/Health/Services/Mental-Health/Strategy

statistically significant. The extension to the study was aimed at increasing the precision of the estimates of benefits and cost effectiveness.

2.3 Objectives of the extended study

The aims in the current study were to obtain additional client QALY data from questionnaires applied in the 2014/15 period in order to:

- ❑ Increase the number of client records from which QALY changes could be derived;
- ❑ Translate the SF-12 scores for the extended period of observation into QALYs:
- ❑ Assess whether a larger sample would deliver statistically significant effects for the intervention; and
- ❑ Use the extended dataset as the basis for new estimates of cost-effectiveness.

The geographical application of Branching Out has changed over time as Forestry Commission Scotland has made the intervention available in a wider set of regions within Scotland. This has meant some change in the referral bodies and in the organisations that deliver the programme. There was evidence for a limited change in the type of clients with more referrals from community organisations than NHS bodies. Clients referred by community organisations are likely to have less severe conditions (mild depression and anxiety) rather than the typically severe and enduring psychotic condition of many NHS referrals. It was not possible to 'type' clients by pre-programme condition because of confidentiality constraints but we tested for any effects of client type and pre-programme SF-6D dimensions.

The delivery of the programme was standardised as far as possible by all delivery staff undergoing a uniform training programme. However, it was decided not to include the 2007/08 in the pooled analysis because of possible changes in the type of clients referred and the delivery of the scheme subsequent to that investigation.

3 Updated literature review

3.1 Relevant lliterature

Natural England has recently published an extensive review of nature-based interventions for mental health care (Bragg and Atkins, 2016). However the report contains almost no quantitative evidence on the cost or effectiveness of such interventions. It does not therefore assist in the economic analysis of interventions to support mental health in terms of their cost-effectiveness within a QALY framework. More generally, cost-utility analysis (CUA) and cost-effectiveness analysis (CEA) are being increasingly used to analyse the costs and effects of treating both physical and mental illnesses.

Among the most widely used HRQoL and utility measures are the SF-6D (derived from the SF12 HRQoL measure) and the EQ 5D. Both have been used in mental health populations. The EQ-5D is more geared to physical health QALY assessment. The SF-6D provides both mental and physical health utility measures.

It may be that generic preference-based methods such as SF-12 and EQ-5D are less appropriate or sensitive in some medical conditions. This has led to concerns being expressed, especially in the area of mental health, that generic preference-based methods may lack sensitivity in capturing important elements of health-related quality of life (HRQoL), due to their focus on physical aspects of health: 4 out of 5 items of EQ-5D capture physical aspects of HRQoL. SF-6D has six dimensions: physical functioning, role limitations, social functioning, pain, mental health, and vitality. This has led to proposals for the development of a preference-based method specific to mental health.

Papageorgiou et al (2013) investigated the McSad depression specific classification system among patients with somatic conditions. It proved to be valid and it appeared to perform considerably better than the EQ-5D classification system, explaining a greater proportion of variance in depression. Papageorgiou et al (2013) concluded that the McSad instrument should be used in future valuation studies to assess intervention amongst patients with somatic conditions, since it reflects a range of depression states for those who experience a chronic medical condition.

In another study, Mavranezouli et al (2011) and Mavranezouli (2013) investigated the applicability of using the Core Outcomes in Routine Clinical Evaluation – Outcome Measure (CORE-OM) as a preference based method to suitable across a range of health conditions. CORE-OM is a patient-based instrument that is used in the UK to evaluate the effectiveness of psychological therapies in people with common mental disorders. It consists of 34 items, each with 5 levels of response (ranging from 'not at all' to 'most or all the time'), tapping 4 conceptual domains: 'subjective well-being', 'problems', 'functioning' and 'risk'. CORE-OM is a patient-based instrument that is becoming more widely used in the UK to evaluate the effectiveness of psychological therapies in people with common mental disorders. However, Mavranezouli et al (2011) found that one limitation of the measure is that it is only suitable for common mental disorders, such as depression and anxiety. CORE-OM has not been designed for use in other mental disorders such as schizophrenia, bipolar disorder, personality disorders etc. Consequently, CORE-6D cannot be used to estimate QALYs in evaluations of interventions targeted at mental disorders other than depression and anxiety, and therefore cannot be used as a 'generic' mental health preference based method.

Bennett et al (2000) report the McSad utility measure for depression. The measure is based on four levels across six dimensions: emotion (mood), self-appraisal, cognition, physiology (sleep, energy level, appetite), behaviour (ability to do things),

role function (at work, at home, with friends). It is thus more tailored to mental health dimensions than SF-12. The McSad utility scores provide weights to calculate QALYs. Scores from McSad reported by Bennett et al (2000) were 0.59 for mild depression and 0.32 for moderate depression. Thus for an individual with a 20 year life expectation, the QALY figure for spending the next 20 years in a moderate depression health state is (20 * 0.32 =) 6.6 years. If the individual moved (through intervention) to a mild depression health state, then the QALY would be (20 * 0.59 =) 11.8 years. Thus intervention resulted in a (11.8 – 6.6 =) 5.2 QALY gain. On this scale mild depression is in the same range as kidney dialysis, while the utility for moderate depression is below that reported for being blind, deaf, or dumb. For severe depression Bennett et al (2000) estimated a utility score of 0.09.

Research has sought to investigate the costs of supporting individuals with psychiatric disorders, taking a more broad cost perspective. Beecham (2014) reviews child and adolescent mental health problems. For these individuals, health services provide an important contribution to health: children with psychiatric disorders often require additional educational support. The justice system may also bear considerable costs for some adolescents, whilst families may have to bear some support costs, and incur lost employment and additional time spent caring. Beecham (2014) reveals differences in costs for children and adolescents with different mental disorders: autistic spectrum disorder; attention deficiency hyperactivity disorder; conduct disorder; and anxiety and depression. In the review of studies Beecham (2004) notes the difficulty of comparing studies and arriving at definitive cost estimates. Different studies use different outcome measures, there are differences in interventions, and differences in health care organisation and financing systems, as well as practical difficulties of deciding when parental care ends and additional support due to the disorder should begin.

Of course, Branching Out participants are adults rather than adolescents. Adults with mental health issues may have lower educational and justice system costs than adolescents, but utility cost to individual patients may be just as great. Roberts et al (2014) from a sample of 5,688 individuals in 2000 and 5,388 in 2007, estimated an SF-6D score, for those with no physical and no mental health problems, of 0.829 and 0.827 respectively. Long term depression and depression sufferers had low scores of 0.532 and 0.551 respectively. But there were three mental health conditions that were not statistically significant: psychosis, personality disorder, and alcohol dependence, although the lack of statistical significance for psychosis and personality disorder may have been due to the small number of people in the sample (81n and 31 respectively) suffering from these conditions.

The Roberts et al (2014) results from a sample of over 10,000 responses reveal statistically significant and large adverse effects on health utility for all but three mental health conditions. Depression, mixed anxiety depressive disorder, and generalised anxiety disorder, impacted most on health. The health effects reported in the survey from a computer assisted personal interview, and from second stage interviews using trained psychologists, are larger than those from self-reported physical health conditions. Roberts et al (2014) also pointed out that coefficients on all interaction terms between mental co-morbidities (e.g. generalised anxiety disorder * depression) are positive, implying that having two conditions results in a health decrement that is less than the sum of the individual coefficients. Interactions effects between physical and mental disorders are also positive, except for that between mixed anxiety depressive disorder * respiratory complaint where the coefficient was negative and statistically significant, implying that having both of these disorders reduces health utility by more than that suggested by the additive utilities for these two disorders.

However, despite concerns about SF-6D, recent research has suggested that SF-6D, and EQ-5D, can be used in economic evaluation of interventions for common mental health problems with some confidence (Mulhern et al, 2014). The study by Mulhern et al, 2003; Mulhern et al, 2014) investigated the psychometric performance of EQ-5D and SF-6D across different mental health conditions (common mental health problems, mixed common mental and personality disorders, schizophrenia, and personality disorders). Seven large data sets were used to assess construct validity and responsiveness to change over time, in comparison with validated condition specific patient-reported outcome measures (PROMs). The results of the study indicate that generic preference-based PROMs are valid for use in common mental health problems, and there is evidence of responsiveness to change over time. However, the psychometric performance in schizophrenia was more inconsistent. Thus for schizophrenia, the measurement of quality of life may be improved by developing a condition-specific preference based measure.

The McSad approach has not yet been fully tested and developed in the UK to assess mental health conditions and estimate QALY values. Moreover CORE-6D cannot be used to estimate QALYs in evaluations of interventions targeted at mental disorders other than depression and anxiety, and therefore cannot be used as a 'generic' mental health preference based method. Recent research has concluded that SF-6D can be used in economic evaluations of interventions for common mental health problems. The earlier Branching Out data (2007/08 and 2011/12) was gathered using SF-12 and this suggests that, despite some limitations SF-6D based estimates of QALYs, those estimated for Branching Out remain valid and reliable assessments of the programme.

4 Analysis of the extended dataset

4.1 Research method

The most rigorous and scientific method to assess the effectiveness of a medical treatment is a randomised clinical trial (RCT). In RCT patients are randomly allocated to receive a treatment or a placebo group. The "*with* treatment" group can then be compared to the "*without* treatment" group. The advantage of randomization is that it minimizes self-selection bias, allocation bias, and balances both known and unknown prognostic factors, in the assignment of treatments. It eliminates bias in treatment assignment; masks the identity of treatments from participants, investigators and assessors; and permits the use of probability theory to estimate the likelihood that any difference in outcome between treatment groups could have arisen by chance.

Unfortunately it was not possible adopt such a rigorous approach in the Branching Out study. There is no obvious "placebo" to Branching Out (where participants thought they were receiving Branching Out treatment, but did not in fact do so). Participants were selected if the health care provider thought the patient would benefit from attending Branching Out. Moreover, patients could not be randomly allocated to Branching Out or to conventional care: patients themselves had to elect whether to attend Branching Out. This self-selection may have resulted in some unknown degree of bias in treatment assignment.

The methodology adopted was a *before* and *after* approach. Participants on the Branching Out programme were subject to a health related quality of life assessment before commencing the treatment (Branching Out), and to identical assessments at the end of the programme and at 3 months after completing the programme. A before-and-after study is rigorous if the exogenous variables, other than the experimental treatment, remain unchanged throughout the period of the study.

4.2 Questionnaires and samples

The SF-12 questionnaire[6] was applied in 2014/15, as in 2011/12, at three stages of the programme:

- ❑ Pre-programme
- ❑ Immediate post-programme
- ❑ 3-month post-programme

Sample characteristics

The total sample provided by FCS in 2014/15 was 359 participants. However, not all 359 participants completed both the pre- and post-course SF-12 questionnaires: only 102 participants completed both pre and post SF-12 questionnaires. Nevertheless, there appeared to be little difference between the two groups: the mean age was quite similar, as was the gender division. The most observable difference was in the mean number of weeks attended by participants: those completing both the pre and post- SF-12 questionnaires were more likely to attend more weeks of the Branching Out course.

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[6] For information on the structure of this questionnaire and its domains see:
Larson. C. CO (2002). Use of the SF-12 Instrument for Measuring the Health of Homeless Persons. Health Serv Res. Jun; 37(3): 733–750.

Table 4.1: Demographic characteristics of participants in the 2014/15 sample.

Variable	N	All sample (359)	N	Pre- and post-programme SF-12 completions (103)
Age (mean)	305	42.78	101	44.16
Gender	355	69.01% (male)	102	69.61% (male)
Weeks attended	165	9.22	96	10.19
Course length	358	11.60	103	12.00

Note: Not all questionnaires were fully completed which explains the differences in N for the attributes:

The analysis of the previous 2007/08 and the 2011/12 data sets was based on participants who had completed both pre- and post-SF-12 questionnaires. To maintain consistency the analysis of the 2014/15 dataset was also based on this group of 102 participants. But as Table 4.1 shows there is little to suggest that participants completing the pre- and post-course SF-12 questionnaire were significantly different from the entire sample of 359 participants.

The mean age (n=101) of the 2014/15 sample of the 102 participants was 44.16 years (st dev = 11.83 years). The youngest participant was 20 and the oldest 69. Males comprised 69.6% of the sample (n=102). The average number of weeks attended (n=95) was 10.2 (st dev = 2.59), with 47 participants (49.5%) reporting the maximum 12 attendances. 80 participants (84.2%) (n=96) attended 8 or more of the 12 weeks of the course.

These characteristics are similar to the previous pooled data set of participants attending Branching Out in 2007/08 and 2011/12. This data for the pooled 2007/08 and 2011/12 data sets, where both pre and post- SF-12 scores were available, provided a sample of 150 participants. The average age of participants in this pooled data set was 41.60 years (st dev = 10.5 years) (n=146). The youngest participant was 21 years old and the oldest 66 years. Males comprised 64.7% of the sample, and females 35.3% (n=150). The average number of weeks participants attended the Branching Out course was 9.8 (st dev = 2.16) (n=150), with 36 participants reporting the maximum 12 attendances. 88.7% of the 150 participants attended eight or more of the 12 weeks of the course.

4.3 Effects of the programme on SF-12 and SF6-D indicators

The SF-12 was used to generate a 6 dimensional health state classification utility score (SF-6D). An SF-6D score is inversely related to an SF-12 score: higher scores on SF-12 indicate a better health state, whilst a higher SF-6D score indicates a worse health state. The rationale for converting the SF-12 scores to SF-6D scores is that SF-6D scores are utility scores – large population studies allow us to estimate perceived utility of the different health states expressed by different SF-6D scores. From these differences in value of health states QALY values can be calculated based on the work of Brazier and Roberts (2004).

Pre- and post-Branching Out SF-6D health scores for participants completing the pre and post course HRQoL questionnaires (2014/15), as well as those for the 2007/08 and 2011/12 groups, are presented in Table 4.2. This reveals that the health utility scores improved[7] across three dimensions (SFSocial, SFMental, and SFVital) in the 2014/15 sample, after the Branching Out course. That is, the SF-6D scores were on

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[7] An improvement is indicated by lower SF-6D scores in the table.

average lower post-course compared with pre-course scores. However, for the other three dimensions (SFPhys, SFRole, and SFPain) the HRQoL deteriorated: for these dimensions the post-course scores were higher than the pre-course scores on average.

In the earlier period (2011/12) there is an improvement in the post Branching Out scores relative to the pre-Branching Out scores across all measures (role; social functioning; mental health; vitality; and pain) except for physical functioning. The improvement in the mental health score is quite noticeable. In contrast, the first tranche of data (2007/08) exhibits a deterioration in post Branching Out health scores relative to pre Branching Out health scores across all indices except for mental health.

The pre-Branching Out scores for health measures were higher in the 2011/12 period than in the 2007/08 period (except for the score for "pain") and in the 2014/15 period (except for the score for SFPhys). This suggests that the health state of participants was worse for those commencing the Branching Out courses in 2011/12 compared with other periods.

The improvement in the mental health score was much greater amongst participants in the 2011/12 period than amongst participants in the earlier 2007/08 period or in the later 2014/15 period. This may be because there was more scope for improvement in patients' health in the 2011/12 period, or because of possible changes in the Branching Out course in the 2011/12 period.

Table 4.2: Mean pre and post- scores for health dimensions: SF-6D scores

	Pooled data 2011-15		2011/12 data		2014-/15 data	
	Pre-	Post-	Pre-	Post-	Pre-	Post-
SFPhys	1.457 (0.594)	1.526 (0.614)	1.425 (0.575)	1.452 (0.578)	1.480 (0.609)	1.578 (0.636)
SFRole	3.463 (0.987)	3.377 (1.043)	3.753 (0.662)	3.466 (0.944)	3.255 (1.123)	3.314 (1.108)
SFSocial	3.011 (1.139)	2.789 (1.168)	3.164 (1.067)	2.740 (1.093)	2.902 (1.182)	2.824 (1.222)
SFMental	2.931 (1.102)	2.680 (0.994)	3.219 (1.017)	2.740 (0.943)	2.725 (1.118)	2.637 (1.032)
SFVital	3.160 (1.092)	2.800 (1.077)	3.384 (1.009)	2.795 (1.067)	3.000 (1.126)	2.804 (1.090)
SFPain	2.160 (1.197)	2.183 (1.170)	2.247 (1.199)	2.110 (1.149)	2.098 (1.198)	2.235 (1.187)
N=	175	175	73	73	102	102

Standard deviation ( ). Phys=physical functioning; Role=limitations; Social=social functioning; Mental=mental health; Vital=vitality; Pain=pain.

The pre-course scores for all dimensions except SFPhys, indicated a higher HRQoL for the 2014/15 participants before the start of the course compared with 2011/12 participants. Thus there was less scope for improvement in patients' health in the 2014/15 period compared to the 2011/12 period.

There are other possible reasons that might explain the changes in pre and post-course SF-6D scores over time. These include variations in the proportions of

patients with different psychotic conditions referred in different time periods. The Branching Out course may be more successful in improving the HRQoL for patients with particular psychotic conditions.

The immediate post Branching Out scores for the pooled dataset indicate a slight deterioration in SFPhys (physical functioning) [post score > pre score], SFRole, and an increase in SFPain. By contrast there were much larger improvements in SFSocial (social functioning), SFMental (mental health), and SFVital (vitality).

4.4 Quality Adjusted Life Years (QALYs)

Converting the SF-6D utility scores to QALYs provided a QALY improvement (pre-Branching Out minus post-Branching Out QALY scores) of +0.00347 per participant in the period 2014/15. This differs from the mean QALY change for each of the other sample periods. The mean QALY changes, with standard deviation, and minimum and maximum individual participant QALY change after the Branching Out course, are set out in Table 4.3.

The mean QALY change per participant was higher in the 2011/12 period than in the 2014/15 period. The 2014/15 period was characterised by a greater dispersion of individual QALY scores: the minimum and maximum scores were larger in 2014/15 than in the period 2007/08 and 20011-12. This suggests than in the period 2014/15 some participants benefitted much more from Branching Out in terms of the course stimulating a HRQoL improvement, but conversely for some participants the HRQoL was lower after the Branching Out course in the 2014/15 period than in 2007/08 and 2014/15 periods.

This implies that greater discrimination ought to be exercised in selecting participants for the Branching Out course to ensure only those with a greater probability of benefitting from the course are selected. This will ensure a larger positive difference in the pre- and post-QALY scores.

Table 4.3: QALY scores attributable to the Branching Out programme over two periods

Period	N	Mean QALY change	St deviation	Minimum QALY change	Maximum QALY change	Number with QALY improvement	Number with QALY deterioration	Number with no QALY change
2011/12	73	+0.04955	0.10448	-0.14000	+0.37600	42	25	6
2014/15	102	+0.00347	0.11057	-0.29900	+0.42400	48	41	13
2011-15	175	+0.02269	0.11015	-0.29900	+0.42400	90	66	19

4.5 Statistical significance of the effects

The statistical significance of the difference between the pre- and post-course QALY scores can be tested using a parametric test such as a 't' test if the distribution is assumed to be normal, or a non-parametric test if a parametric assumption cannot be made (Siegel, 1956). Since HRQoL data is based on ordinal scores (e.g. 1 to 5) a non-parametric test of significance may be more appropriate for changes in QALYs derived from HRQoL scores, rather than a parametric test of significance which assumes a normal distribution.[8] Two non-parametric tests were used: a matched-pairs sign test, and a Wilcoxon matched-pair sign rank test. In the sign test the null hypothesis is that given a pair of measurements x_i and y_i (i.e. pre and post QALY scores) are equally likely to be larger than the other. If Branching Out increased QALYs then the null hypothesis should be rejected: the post scores should indicate a higher HRQoL (and QALY) than the pre-scores. The Wilcoxon matched-pair sign rank test takes into account the magnitude (rank) of the difference between measurements x_i and y_i as well as the sign.

The statistical significance of the QALY improvement attributable to Branching Out is shown in Table 4.4, over different time periods. The QALY improvement amongst participants in the 2011/12 period was statistically significant on the basis of a Student's 't' test and the Wilcoxon rank test, and just significant at the 5% level on the basis of the Wilcoxon sign test. This occurred because during this period many more participants recorded positive QALY gains from the Branching Out course than participants who suffered a QALY decline, compared with the other two periods. In addition during the 2011/12 period for those who suffered a QALY deterioration, this QALY deterioration was less than the magnitude of deterioration in the other periods, thus contributing to the statistical significance of the Wilcoxon rank test during the 2011/12 period.

The QALY improvement for participants attending Branching Out courses during 2014/15 was not statistically significant on any of the statistical significance tests nor was the improvement over 2011-2015.

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[8] The Student's 't' test is the usual parametric test employed which is based on the normal distribution. A paired sample 't' test was used by Wilson (2009) to test the statistical significance of the pre and post HRQoL scores for 2007/08 Branching Out participant sample, but no significant statistical difference was found in the health dimension scores. The Student's 't' test may produce misleading results if the distribution is not normal; or if the data are not sampled independently from the two populations being compared, i.e. if the data are known to be dependently sampled. In such cases the Student's 't' test may suggest there is a statistically significant difference between the two samples when in fact there is none.

Table 4.4: Statistical significance of QALY results over three periods

Period	N	Mean QALY change	't' test	Pr|t|	Wilcoxon sign	Pr |S|	Wilcoxon rank	Pr |R|
2011-12	73	+0.04955	4.051708	0.0001	8.5	0.0498	535	0.0005
2014-15	102	+0.00347	0.316982	0.7519	3.5	0.5250	75.5	0.7593
2011-15	175	+0.02269	2.725072	0.0071	12	0.0652	1376.5	0.0144

However, for the period 2011/12 (73 cases) the mean QALY score for the improvement (=0.04955) attributable to Branching Out is highly statistically significant based on a Wilcoxon matched-pair sign rank test (the sign rank 'p value' = 0.0005); although it is just statistically significant at the 5% level based on the sign test ('p value' = 0.0498).

4.6 QALY effects over different time periods

The improvement masks considerable differences between the datasets for differnet time periods. The 2014/15 results show a small mean QALY gain but this effect was not significant. The 2011/12 clients showed a larger QALY gain at +0.04955.

Table 4.2 shows that participants on the Branching Out course during 2014/15 seemed to be in a better health state generally than those on the programme in 2011/12[9]. It may be that Branching Out is less effective at improving the health states of those less severely affected by mental health problems. Or it may be that the participants during 2014/15 were in an early mental health state, and that the Branching Out programme actually curtailed an even greater deterioration in their mental health. That is, although this 2007/08 programme saw a QALY deterioration, the counter factual (without Branching Out programme) QALY deterioration would have been even greater.

4.7 Duration of the QALY effect

Some evidence on the duration of the QALY arising from the Branching Out programme can be ascertained from an SF-12 questionnaire survey three months after each participant completed the Branching Out course. Unfortunately only a small number of participants completed all three SF-12 questionnaires: pre-, immediate post-course, and 3 month post-course questionnaires. The pre-scores, immediate post-course scores, and the 3 month post-course scores after the Branching Out course ended are reported in Table 4.5.

Comparison of pre- and post-3 month QALY effects

The 2011/12 results are generally not statistically different between pre-, immediate post- and 3 month post-scores. The 3 month post-course scores were higher across all the indices compared to the immediate post-course scores. Indeed, 3 months after completing the course two of the health dimensions (SFPhys and SFPain) of these individuals were worse than their pre-course scores. Although improvements were maintained for SFSocial, SFRole, and SFVital, relative to their pre course scores, whilst SFMental remained unchanged.

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[9] This was also the case with the earlier group of participants (2007/08).

Table 4.5: Mean pre, post and 3 month post-scores for SF-6D scores for those participants who completed the pre-, immediate post-, and 3 months post-course questionnaires (2011/15)

	Mean pre- and post- 3 month scores 2011-12 participants			Mean pre- and post- 3 month scores 2014-15 participants			Mean pre- and post- 3 month scores 2011-15 participants		
	Pre-programme	Post: 0 months	Post: 3 months	Pre-programme	Post: 0 months	Post: 3 months	Pre-programme	Post: 0 months	Post: 3 months
SFPhys	1.429 (0.598)	1.476 (0.512)	1.714 (0.644) 4)	1.479 (0.618)	1.625 (0.640)	1.667 (0.694)	1.464 (0.608)	1.580 (0.604)	1.681 (0.675)
SFRole	3.810 (0.680)	3.429 (1.076)	3.619 (0.805)	3.354 (1.120)	3.313 (1.133)	3.500 (0.945)	3.493 (1.024)	3.348 (1.109)	3.536 (0.901)
SFSocial	3.048 (0.921)	2.571 (0.978)	2.667 (0.966)	2.938 (1.119)	2.833 (1.243)	2.854 (1.304)	2.971 (1.057)	2.754 (1.168)	2.797 (1.208)
SFMental	2.905 (0.995)	2.619 (0.921)	2.905 (0.944)	2.792 (1.110)	2.604 (1.067)	2.875 (1.248)	2.826 (1.070)	2.609 (1.018)	2.884 (1.157)
SFVital	3.333 (0.796)	2.667 (0.913)	3.143 (0.964)	3.125 (1.123)	2.896 (1.096)	3.250 (1.194)	3.188 (1.033)	2.826 (1.048)	3.217 (1.123)
SFPain	1.952 (1.161)	2.095 (1.179)	2.429 (1.287)	2.188 (1.161)	2.292 (1.184)	2.250 (1.158)	2.116 (1.157)	2.232 (1.178)	2.304 (1.192)
N=	21	21	21	48	48	48	69	69	69

Standard deviation ( )

Phys=physical functioning; Role=limitations; Social=social functioning; Mental=mental health; Vital=vitality; Pain=pain.

A similar picture emerges in the 2014/15 data set.[10] Post-completion 3 month scores were higher (worse) than the immediate course completion course scores across all indices, except for SFPain. Also, the post-completion 3 month scores were higher (worse) than the pre-course scores across all indices, except for SFSocial. This may be indicative that the health of patients was deteriorating, and that the Branching Out course prevented a deterioration in patients' health whilst patients attended the course. Unfortunately this hypothesis, that Branching Out prevented an even greater deterioration in health than that recorded by the before and after HRQoL data, could not be tested. Such a test would require a control group who did not participate in a Branching Out course.

The difference between the pre- and immediate post-course QALYscores for participants (who also completed the post-3 month questionnaire) in 2011-12 was +0.0478 (st dev = 0.1157), indicating a QALY improvement. The 3 month post course completing QALY was -0.0051 (st dev = 0.0719) indicating that 3 months after completing the course these patients were slightly worse in terms of health status than they were before the course started. In other words the Branching Out course improved the health status of these patients but only for a limited time period.

The immediate post course QALY score for participants (who also completed the post 3 month questionnaire) in 2014-15 was +0.0135 (st dev = 0.0855), indicating a QALY improvement. There were 27 participants who recorded a positive QALY gain, and 16 who recorded a negative QALY change, with 5 participants recording no QALY change. The 3 month post course completing QALY was -0.0137 (st dev = 0.1083) indicating that 3 months after completing the course these patients were slightly worse in terms of health status than they were before the course started. At the post 3 month date, only 19 participants recorded a positive QALY gain, whilst 22 now recorded a negative QALY change, and 7 participants recorded no QALY change. Again, the Branching Out course improved the health status of the patients but only for a limited number of patients.

A similar picture emerges for the pooled data set (2011-15). Here the pre-immediate post course difference in the QALY score was +0.0239 (st dev = 0.0961) (n=69). This QALY difference is statistically significant at the 5% level across all statistical tests (Student's 't' = 2.0682, Pr|t| = 0.0423; Wilcoxon sign test = 9, PR|S| = 0.0273; Wilcoxon sign rank = 272, Pr|R| = 0.0442).

The pre – post 3 month course QALY change was -0.0111 for the pooled 2011/15 data (n=69). This QALY difference of -0.0111 is not statistically significant even at the 10% level across all statistical significance tests (Student's 't' test, Wilcoxon sign test, and Wilcoxon sign rank test). Again the data suggests that the Branching Out course led to a HRQoL QALY improvement, but that this improvement was of a limited duration in time. However, a full test of the duration of any QALY improvement really requires a control trial; that is, a sample of patients who did not participate in Branching Out to compare with those who did participate.

4.8 Factors affecting the benefits from Branching Out

The cost-effectiveness of the Branching Out course would be improved if participants were selected who were more likely to have positive QALY changes between pre- and immediate post-course assessments; or if participants were selected who were more likely to have larger QALY changes between pre- and immediate post-course assessments.

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[10] For the 2014-15 data set, the difference in SFMental between pre- and immediate post- scores was statistically significant at the 1% level. The difference in SFVital between pre and immediate post-scores was statistically significant at the 10% level on the Student's 't' test and the Wilcoxon sign rank test, but was only statistically significantly different at the 15% level on the Wilcoxon sign test. Other differences between SFPhys, SFRole, SFSocial, and SFPain were not significant between pre- and immediate post-scores.

An attempt to understand which factors might drive positive and larger QALY improvements was made using a logistic regression (to predict positive and negative QALY changes) and by an ordinary least squares (OLS) regression[11] to model the magnitude of QALY changes. The 2011-15 data sets provided 175 observations (102 for 2014-15, and 73 for 2011-12) on QALY changes between pre and immediate post course assessments. Of these 133 observations were used in the analysis, due to missing observations for some participants on age, number of weeks the Branching Out course was attended, and type of patient.

The variables used in the analysis were:

- gender ('male')[12]
- age ('age')
- number of weeks attended ('watt')
- client type: whether the participant was from a mental health resource centre ('medr'), or was an outpatient or inpatient at a hospital ('medp')
- the participant's QALY level at the start of the course ('preqaly')
- the participant's SF-6D mental score at the start of the course ('mental')
- the participant's SF-6D vitality score at the start of the course ('vital')
- the participant's SF-6D social role score at the start of the course ('role').

In the logistic model ultimately selected (see Annex 1) the relationship of 'mental' score to QALY gain after participation in Branching Out was positive and highly significant statistically. There was also evidence for greater improvement among those with lower 'vital' scores although this was less significant. It can be concluded that the worse the pre-programme mental state and lower the vitality, the greater the probability of a QALY gain from participation. None of the other parameters were statistically significant[13]. Hence, there was no indication that age, gender or referring type affected programme outcomes.

Similar results were found with the OLS regression model (see Annex 1). The 'mental' variable was highly significant and 'vital' was significant at $p<0.1$ indicating that those in the poorest mental and vital states pre-programme showed the largest health benefit as measured by the change in QALY during the programme.

Hence the pre-course condition of the participant as measured by 'mental' and 'vital' appear important in determining the gains in quality of life during the course. Those with poor states as measured by these SF-12 dimensions benefit most. If these states could be related to the type and severity of the psychotic disorder suffered by patients there may be more scope for identifying those for whom Branching Out offers the greatest benefit. Although the broad referral categories used in the study (inpatient/outpatient, community referral or mental health centre referral) were not significantly related to differences in outcome, further exploration of referral pathways might provide stronger predictors of characteristics of clients who benefit from Branching Out.

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[11] These statistical methods are described in Tabachnick, B. and Fidell, L. (2001). Using Multivariate Statistics. Allyn and Bacon, Boston.
[12] Gender (male) was modelled relative to female; whilst client type was modelled relative to participants from an "Other Community".
[13] 'preqaly' and 'role' were significant only if 'mental' and 'vital' were excluded.

5 Benefits and cost-effectiveness of the Branching Out programme.

5.1 Benefits in Quality Adjusted Life Years

The mean QALY score for the improvement attributable to Branching Out based on the pooled (2011/12) data of 0.04955 (Table 4.3) suggests an average economic value of £1,486 per person completing the Branching Out course, based on the NICE QALY value of £30,000[14]. However, usidn the pooed 2011-2014 data the benefit drops to £681 per person.

There are some caveats to this economic value of the Branching Out programme. The health state improvement was measured immediately after the Branching Out course was completed. The mean QALY values are based on a one year improvement: a quality adjusted life <u>year</u>. The estimated value of that is £681 per person (2011-2014 period), assuming the health improvement, attributable to Branching Out, lasts one year. In reality the mental health improvement may not last one year, or it may continue for more than one year. If the improvement lasted only 6 months then the QALY value would be 50% of the values indicated in above.

5.2 Costs and cost-effectiveness of the programme

In the previous report the 2011/12 costs were estimated at £426 per person attending at least one session. With a mean QALY gain of 0.0495 the cost per QALY was £8,600.

In the 2014/15 year we used the same basis for calculating costs In order to estimate the cost-effectiveness of continuing the programme. These are summarised in Table 5.1 and include FCS staff, travel and set-up costs, together with payments to delivery agents and referring agency costs. The cost per user was slightly lower in 2014/15, averaging £392 per user (Table 5.1). This was mainly due to a reduction in the cost of delivery agents. FCS increased their element of delivery with a corresponding increase in staff costs.

Table 5.1: Financial costs of Branching Out (2014/15 year)

	£ per year
FCS staff costs	34,437
Delivery agents' costs	75,702
FCS set-up costs	401
Referring agency costs	0
FCS travel costs	4,174
Service users' costs	0
Total	£121,617
Total per user (n=310)	£392.30

The financial cost-effectiveness of the programme is defined here as the cost per QALY improvement in HRQoL. It is measured as the mean QALY improvement per person divided by the cost per person. Based on 310 service users per year, and using the estimated QALY benefits over the 2011/15 period, the cost per QALY is £17,276[15]. This is based on a

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[14] This is the maximum cost per QALY applied by NICE as a guide to cost-effective intervention.
[15] We excluded the 2007/08 data since it was derived from an earlier and separate study made during the early stages in the development of the Branching Out programme.

mean QALY change of +0.02269 and a cost per participant of £392. As judged by the NICE threshold of £30,000 per QALY the programme is cost-effective if its impacts lasts a year.

Comparison of 2011/12 and 2014/15

Based on the pooled QALY gain over 2011-2015 the cost-effectiveness of the programme was lower in 2014/15 than in 2011/12 (£17.3K compared with £8.6K per QALY). Nevertheless, the programme remained cost-effective over its 12 week intervention as assessed against the NICE £30,000 per QALY benchmark.

We were unable to throw much light on the longer-term benefits of the programme because of the very limited number of questionnaires that were returned 3 months after the end of the programme. The evidence suggests that benefits may not be maintained and that Branching Out has to be seen as one stage in a sequence of intervention measures in order to build on the shorter term benefits.

5.3   Retention rates under the programme

The retention rates of participants in the branching Out programme can be compared with those reported in other studies of community-based mental health interventions. Comparison is difficult because there are is no commonly accepted measure of retention rate and not all studies provide information from which retention measures can be derived. The studies listed in Table 5.2 are considered typical of broadly comparable interventions. The table shows retention results from five studies among adults with enduring mental health problems.

Table 5.2: Retention rates in mental health programmes

Programme	Referred No.	Attended > 0 sessions N %	Attended >4 /completed	Type of programme
Branching Out 2007-15	2,050	1,830 (89%)	1,436 (70%)	Adjunct service for clients referred through Scottish mental health services.
Richards and Borglin (2011)	7,859	5,717 (73%)	2,949 (38%)	Stepped care (IAPT*) supporting psychological therapies for anxiety and depression
Alegria et al (2014)	372	300 (81%)	234 (63%)	13 community outpatient clinics, effective self management mental health.
Richardson et al (2005)	39	34 (87%)	12 (31%)	Increasing physical activity among patients with enduring mental health problems.
Pentecost et al (2015)	60	20 (33%)		Combining behavioural activation with physical activity promotion for adults with depression:

Note* Improving Access to Psychological Therapies service, UK.

The Table indicates that the initial attendance and retention rates (>4 sessions completed) were higher in the Branching Out programme than in the comparators. This is despite the possible occurrence of adverse weather associated with outdoor activity which might be expected to have a negative impact on attendance. High retention rates are an indicator of satisfaction with the intervention on the part of those participating.

5.4   Comparison of cost-effectiveness

The cost-effectiveness of Branching Out can, in principle, be compared with that for other comparable interventions. However, this is not straightforward because Branching Out does

not substitute for other medication and the extent to which it is used as a substitute for other on-going intervention(s) is unclear. It is best regarded as an adjunct therapy. Branching Out seeks to promote additional benefits by way of physical functioning, social functioning, role participation, and vitality.

Nevertheless, we examined the NICE website to investigate what cost per QALY data were available on medication and other therapies likely to be received by clients. Due to ethical constraints the information available to us on treatments being received by Branching Out clients was limited. Treatments included a wide range of antidepressants, anxiety medication, mood stabilizers and antipsychotics alongside a number of group therapy and behavioural treatments (such as psychotherapy, CBT and mindfulness).

NICE reviews

The NICE website does not appear to have a definitive list of the cost per QALY for conventional drug treatments for different mental illnesses. The website lists many research studies, several of which report QALY cost values for various pharmaceutical therapies. Some of these relate to specific cohorts of patients with mental health illnesses (e.g. young adolescences, mothers with post-natal depression, drug users, patients with HIV, etc) which are not typical of Branching Out groups. The NICE website also lists some studies of cognitive behavioural therapies (CBT) as additions to conventional drug therapies for mental illnesses.

NICE Appendix 15. Evidence Tables for Economic Studies tabulates various studies (e.g. Kendrick 2006; and Benedict 2010) some of which report cost per QALY for drug treatments. Invariably the effectiveness of a particular drug is evaluated with reference to other drug treatments for specific mental illnesses.

Kendrick (2006) studied adults diagnosed with depression. Patients accepting antidepressant treatment were also eligible, including those with comorbid physical or mental illness and those aged over 65 years. The case study was of UK primary care. In this study the incremental cost per QALY gained was £5,686 with Selective Serotonin Inhibitor (SSRI) over Lofexidine (LOF) and £2,692 with SSRI over Tricyclic Antidepressants TCA, while TCA was dominant in comparison with LOF.

Benedict (2010), found in a study of patients in Scotland, that duloxetine compared to mirtazapine and SSRIs produced additional benefits at higher costs leading to incremental cost effectiveness ratios (ICERs) of approx. £2,400 and £6,300/ QALY. If the willingness to pay per QALY gained is below £5000, SSRIs are the preferred treatment choice. Above that value duloxetine is the preferred option in the base case. At a NICE willingness to pay threshold of £20,000, duloxetine would be the preferred option for treatment of Major Depressive Disorder (MDD) in primary care.

One NICE (2015) report concluded that "economic analysis concluded that sertraline was the most cost-effective drug for people with generalised anxiety disorder (GAD) because it was associated with the highest number of quality-adjusted life years (QALYs) gained and the lowest total costs amongst all treatments assessed, including no treatment." However, no details were provided for the cost per QALY for this drug treatment.

Furiak et al (2016) report an American study of the cost-effectiveness of five oral antipsychotics (olanzapine, risperidone, quetiapine, ziprasidone, and aripiprazole) frequently used to treat community-dwelling patients with schizophrenia. The average QALY gain per patient over one year was: 0.731 for olanzapine, 0.717 for risperidone, 0.706 for quetiapine, 0.711 for ziprasidone, and 0.713 for aripiprazole, with mean costs per patient of USD $8,544, $9,080, $13,619, $11,414, and $11,603 respectively. The costs included medications, hospitalisation, emergency room visits, physician visits, mental health clinic visits, home care, group interventions, and nutritionist visits, and were at 2007 prices.

Furiak et al (2016) report another American study of the cost-effectiveness of olanzapine long-acting injection (LAI) in the treatment of patients with schizophrenia. They report mean QALYs gained per patient of 0.677 for oral olanzapine, and 0.711 for olanzapine-LAI, with mean direct medial costs per patient of USD $13,151 and $14,063 respectively. The study also found that paliperidone-LAI, risperidone-LAI, and haloperidone-LAI were all more costly and less effective than oral olanzapine and olanzapine-LAI. Costs comprised in-patient treatment, day hospital treatment, physician visits, mental health clinic visits, home care, group interventions, nutritionist visits, nurse visits, and ambulance transport, at 2009 prices.

The Centre for Economic Performance: London School of Economics (CEP, 2012) points to the high clinical effectiveness of many mental health treatments, as indicated by the Numbers Needed to Treat in order to achieve one successful outcome, and by the cost-effectiveness as measured by cost per QALY. The report provides some estimates of the cost per QALY for different treatments, for the effectiveness of cognitive behavioural therapy (CBT) against alternative treatments (Table 5.3). However, the report provides no information on how a placebo could be administered in place of CBT, nor what 'treatment as usual' comprised the alternative treatments for various mental disorders.

Table 5.3: Some QALY estimates of various cognitive behavioural therapies

Mental illness	treatment	Number need to treat	Cost per additional QALY (£)
Depression	CBT v placebo	2	6,700
Social anxiety disorder	CBT v treatment as usual (TAU)	2	9,600
Post-natal depression	Interpersonal therapy v TAU	5	4,500
Obsessive compulsive disorder	CBT v TAU	3	21,000

Source: CEP (2012).

Hollinghurst et al (2010) investigated therapist-delivered online cognitive behavioural therapy (CBT) for patients with depression who were in primary care, compared to usual care (face-to-face CBT). 149 patients took part in online CBT. They were offered up to 10 sessions of 55 minutes each, communicating by instant messaging. Whilst online CBT was more expensive than ordinary care, the cost per QALY gained was £17,173 for completed case data. Online CBT delivered by a therapist in real time was seen to be cost-effective compared with usual care if society was willing to pay at least £20,000 per QALY.

Wiles et al (2016) undertook a study of patients whose depression had not responded to antidepressants. Cognitive behavioural therapy was provided as an adjunct to usual care that included medication over a 3 to 5 years in primary care patients with treatment-resistant depression. Follow-up was, on average, 40 months after therapy ended. The incremental cost-effectiveness ratio was £5,374 per QALY gain. This represented a 92% probability of being cost-effective at the NICE QALY threshold of £20,000.

A review of the cost effectiveness of interventions to promote physical health of people with mental health problems by Park et al (2013) reported a number of QALY values. These ranged from a cost of £20,834 per QALY for patients in primary care with a recent or new episode of depression; and a cost per QALY of £10,276 for a tailored programme delivered in a leisure centre supervised by a qualified exercise professional.

Conclusions

As indicated above we do not consider QALY cost comparisons with specific drugs as relevant because Branching Out is not a substitute medication. Even so, a brief study of the literature reviewed by NICE indicates a wide range in cost per QALY for a range of drugs

with many indicating a cost per QALY well below the £30,000 threshold. Comparison with other therapies including group therapies, CBT and psychotherapies is also difficult because the many are applied to specific conditions which may not be those exhibited by Branching Out clients. The QALY costs of these therapies showed considerable variation, with Branching Out falling within the general range of cost per QALY

6 Discussion and conclusions

The extension to the study produced 102 additional records on the effect of the Branching Out programme. The 2014/15 results confirmed the previous results which indicated that the programme improved the mental health of participants as assessed by the SF-6D mental health score. The 'social' and 'vital' elements in SF6-D were also improved. This indicates that the mental state of participants improved an average as did their vitality and social role.

It was anticipated that the additional observations would improve the statistical significance of the effects. This was not the case because the size of the QALY benefit was smaller in 2014/15 and the standard deviation higher. Even so, the evidence to date does suggest that the programme remains cost-effective when analysed using the pooled 2011/15 QALY results. However, it was not clear that the benefits from Branching Out were maintained beyond the end of the programme. The small number of returned questionnaires 3 months after completion of the course limits the analysis that was possible on this aspect.

One explanation of the differences in QALY gains between years is that the health status of participants at the start of the programme varied between years. Both the SF-mental and SF-vital of participants pre-course affected the health gains that could be attributed to the programme. Participants with a lower pre-programme SF-mental and lower vitality benefitted most. No other factor (age, gender etc,) was significant is its effect. Improved targeting of the programme to improve its impact would need to identify those with more severe mental conditions and low vitality. Since the type of referring body was not a significant factor in explain QALY gain we are doubtful if agency type will be an effective discriminator. We suggest that this aspect might be usefully explored further in discussion with referral organisations and especially the NHS. The question of how best to maintain the benefits from Branching Out beyond the end of the 3 month course might also be investigated.

All the results need to be interpreted with some caution because there was no control group against which programme success could be measured. It may be that some of the apparent impact was due to parallel treatments or the passage of time. Even so, if other interventions or time were major elements in changing health status one might expect the 3 month post-programme health status to be improved and this was not the case.

In summary, the main conclusions from this extension of the original study are:

- ❑ The programme delivers benefits to participants and these are principally for participants with higher (worse) Mental Health and Vitality scores at entry to the programme. Participants in the 2011-12 cohort had significantly worse initial SF-6D scores for Mental Health and Vitality, and showed greater QALY improvement than participants in the 2014-15 cohort

- ❑ There were substantial differences between the QALY gains in the three cohorts studied (2007/08, 2011/12 and 20014/15). This may be due to the differences in SF-6D Mental Health and Vitality between the cohorts on entry to the programme. .

- ❑ Greater discretion in client selection could in principle be used to increase the cost-effectiveness of Branching Out. It is not clear how this might be achieved in practice but we suggest that any options for better matching what the programme offers to the needs of clients is worth exploring.

- ❑ Programme delivery costs per participant were lower in 2014/15 than in 2011/12 but the QALY gain by participants was also lower.

- ❑ The programme cost-effectiveness in 2014/15 was £17.3K per QALY, based on the 2011-15 mean QALY change attributed to the programme. The evidence on the duration of the benefit delivered by participation was unclear. Were the benefit to be

maintained for a year then the intervention would be judged as cost-effective when assessed against the NICE guideline of £30,000 per QALY. Comparable therapies showed a wide range of costs per QALY with Branching Out falling within the overall range.

❑ Initial attendance and retention rates (>4 sessions completed) were higher in the Branching Out programme than in the comparators. High retention rates are an indicator of satisfaction with the intervention on the part of those participating.

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8 Annex 1

Logistic regression

Parameter	DF	Estimate	Standard error	Chi Square	Pr>Chisq
intercept	1	2.7676	1.3900	3.9644	0.0465
male	1	0.5343	0.4588	1.3561	0.2442
age	1	0.0101	0.0172	03471	0.5557
watt	1	0.0399	0.0689	0.3351	0.5627
mental	1	0.7007	0.1968	12.6746	0.0004
vital	1	0.4501	0.1845	5.9484	0.1475
medr	1	0.0321	0.4232	0.0058	0.9394
medp	1	0.6060	0.6169	0.9648	0.3260

Goodness of fit statistics of model: Generalised Rsquare = 0.1682; Nagelkerke R^2 = 0.2244
Sensitivity rate (true positive rate) = 67%; specificity rate (true negative rate) = 53%, against prior probability of a positive QALY = 0.52

OLS linear regression

Variable	DF	Estimate	Error	T value	Pr>|t|
intercept	1	0.06348	0.06194	1.03	0.30675
male	1	-0.02214	0.02156	-1.03	0.3064
age	1	-0.00097591	0.00079067	-1.23	0.2194
watt	1	-0.00015271	0.00335	-0.05	0.9637
mental	1	0.03330	0.00839	3.97	0.0001
vital	1	0.01554	0.00837	1.86	0.0656
medr	1	-0.00085036	0.01997	0.04	0.9661
medp	1	0.01770	0.02871	0.62	0.5387

R^2=0.1567; Adj R^2 = 0.1094