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Quality assessment of health behaviour change apps using a tool developed from NICE guidance

Running head: Applying NICE Guidance to health behavior change apps in the NHS apps Library

**Quality assessment of a sample of mobile app-based health behavior change interventions using a tool based on the National Institute of Health and Care Excellence behavior change guidance.**

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## **Abstract**

*Objective:* To quality assess a sample of health behavior change apps from the NHS Apps Library using a rating tool based on the 2014 National Institute for Health and Care Excellence behavior change guidance (NICE BCG).

*Methods:* A qualitative analysis of the NICE BCG identified themes and questions for a quality assessment of health behavior change apps. These were refined by further discussion and piloting, and applied by two independent raters to a sample of NHS Library apps (N=49). Disagreements were resolved following discussions with a third rater.

*Results:* Themes identified were; purpose, planning, usability, tailoring, behavior change technique (BCT), maintenance, evaluation, data security and documentation. Overall, purpose of the apps was clear, but evidence for collaboration with users or professionals was lacking. Usability information was poor and tailoring disappointing. Most used recognized BCTs but paid less attention to behavior maintenance than initiation. Information on app evaluation and documentation was sparse.

*Conclusions:* This study furthers the work of the NHS apps library, adapting the NICE (2014) behavior change guidance for quality assessment of behavior change apps.

*Practice Implications:* This study helps lay the foundations for development of a quality assurance tool for mobile health apps aimed at health behavior change.

**Quality assessment of a sample of mobile app-based health behavior change interventions using a tool developed using the National Institute of Health and Care Excellence behavior change guidance.**

**1. Introduction**

The World Health Organization (WHO) estimates that around 63% of deaths globally are a result of lifestyle related diseases [1]. The WHO estimates that by 2020, tobacco will account for 10% of all deaths worldwide [1]. Physical inactivity increases all-cause mortality risk by 20-30%, excessive alcohol use accounts for about 3.8% of deaths worldwide, and an unhealthy diet is linked to heart disease, stroke, diabetes, and cancer [1]. The leading four causes of death in England and Wales (Ischaemic Heart Disease, Cerebrovascular Disease, Cancer, and Chronic Respiratory Disease) are all strongly related to behavior [2]. Other health relevant behaviors include substance misuse, driving behaviors, oral hygiene, and excessive sun exposure [3]. The deaths brought about by many of these health-relevant behaviors often occur as the end point of chronic illnesses at a huge cost to the NHS. Encouraging people to adopt healthier lifestyles, and supporting those who wish to do so, is a desirable goal.

Early papers on health behavior change were plagued by inadequate descriptions of the behavior change techniques (BCT) employed, making replication and evaluation difficult [4]. Researchers sought to address this problem by designing BCT taxonomies [5 - 8]. Michie et al's taxonomy of 93 BCTs allows us to identify and classify the wide range of techniques available and lays the ground work for future systematic reviews to evaluate which of these are most effective [9]. It is beyond the scope of this paper to discuss these in detail here, but reviews of the evidence [10] formed the basis of the National Institute for Health and Care Excellence (NICE) guidelines on approaches to health behavior change [11, 12]. NICE is an independent organization, set up by the UK government in 1999 to help reduce variation in the availability and quality of NHS treatments and care. The NICE behavior change guidance resulted from a 2007 request from the UK Department of Health for guidance on the principles for effective behavior change and is considered further in this paper.

There are a range of media via which health behavior change interventions can be delivered. The advent of the home personal computer and the internet saw a growth of health behavior change interventions being delivered on websites [13]. In recent years, the increased capabilities of mobile phones and tablet computers has seen an explosion in the number of mobile applications or 'apps',

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many of which target health behavior change [14]. Ninety-three percent of UK adults have a mobile phone and 61% have a smartphone [15]. Ninety percent of those who own smartphone are in possession of it 24 hours a day [16]. Mobile phone interventions have many advantages; they are relatively low cost, can be individually tailored in real time, can be combined with other traditional media, and can collect, analyse and relay data back to researchers [17]. They can also provide location data and information on proximity to others, and so could potentially text ex-smokers to warn them if they are at higher risk of smoking, based on their location or proximity to other smokers [18]. Smart phones can be used to estimate mode and speed of travel and thus can be used to track exercise without requiring an additional item of equipment [19].

There are over 1.2 million apps available in both the Apple appstore and the Android market, and over 97,000 related to health and fitness [20]. These apps can be further categorised into those aimed at healthcare professionals (e.g. medical reference apps such as drug formularies), those aimed at patients with specific conditions, such as diabetes (e.g. apps which will inform users of the glycaemic index of certain foods), and those aimed at encouraging healthy behaviors (such as the NHS quit smoking app). Summarising all the health apps currently available is beyond the scope of this paper, but the NHS Apps library [21] is a useful starting point as it has a peer review process to decide which apps merit inclusion.

There is limited evidence for the efficacy of apps for health behavior change. The most recent systematic review on this topic summarized the findings of 75 trials – 59 of which were concerned with disease management and 26 that were aimed specifically at health behavior change [17]. They found that interventions employing text messages increased antiretroviral treatment adherence and significantly improved biochemically verified smoking cessation. There was also some evidence that apps encouraging self-monitoring of diet and exercise reduced waist circumference, and that electronic pedometers increased physical activity and diabetes control.

Despite their many advantages, the use of health behavior change apps have a number of associated problems. Smart phones are less commonly used amongst particular sections of the population, are vulnerable to vested interests, and need to be compatible across a wide range of platforms to maximise uptake. One issue of particular concern is quality control [22]. The NHS Apps library has a peer review process ensuring included apps are relevant to people living in England, use information from a verifiable source, comply with the Data Protection Act, and are clinically safe. In addition to these safeguards, it would be useful to have a quality control process for health behavior change

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apps that would enable potential users and healthcare professionals to ascertain how closely the app developers had considered the NICE behavior change guidance. The overall aim of this study was therefore to quality assess a sample of health behavior change apps using a rating tool based on the 2014 NICE behavior change guidance. Specific objectives were to: a) Develop a rating tool for health-behavior change apps, based on the 2014 NICE behavior change guidance; b) Assess the feasibility of applying the tool to a sample of apps from the NHS Apps Library; and c) Describe the results of applying the tool to this sample of apps.

## **2. Methods**

The lead author analysed the NICE (2014) behavior change guidance to examine which aspects would be relevant for an app quality assessment process (see Appendix 1). Relevant aspects were agreed upon following discussions with the remaining authors. The suggestions in the NICE guidance were converted into questions (that could be answered yes/no) relevant to app quality assessment. Duplicate questions were removed and those remaining were arranged into themes (see Table 1). Two independent raters piloted the questions and met to discuss further refinements. The resulting questions are listed in Tables 2 and 3 (see Appendix 2 for the user manual). Following further discussions to clarify the purpose of the questions, and training in use of the Statistical Package for the Social Sciences (SPSS) [23], these questions were then applied to health behavior change apps in the NHS apps library by two independent researchers. Answers were entered into an SPSS database, and apps were coded using information gleaned from the app description in the library, on the app store and related websites. Percentage agreement between raters was calculated based on the sum of the percentage of answers to which both raters answered 'yes' and to which both raters answered 'no'. Disagreements between raters were resolved by discussions with a third researcher.

## **3. Results**

### ***3.1 Themes in the NICE Behavior change guidance***

Nine themes emerged from the exercise to extract questions from the NICE guidance thought relevant to app quality assessment. These themes related to: 1. The purpose of the app, 2. Planning and development of the app, 3. Usability, 4. Initial assessment and tailoring, 5. Behavior change techniques employed, 6. Behavioral maintenance and relapse prevention, 7. Evaluation of the app, 8. Documentation, and 9. Data protection. Table 1 shows an example question for each theme, with tables 2 and 3 containing the full set of questions used in the final tool.

### ***3.2 Selecting the apps from the NHS Apps Library***

The NHS apps library contains 223 apps, 167 of which are on the Apple platform, 95 on Android, 7 on Windows, 2 on Blackberry, and 62 of which are mobile-compatible websites. Apps submitted by developers are assessed by the library's clinical assurance team (consisting of doctors, nurses and safety specialists). **On their website, the NHS Apps library states the review process ensures that apps "are relevant to people living in England, comply with data protection laws and comply with trusted sources of information, such as NHS Choices" [21].** Any apps deemed to have the potential to cause harm require further development before they would be considered for inclusion. To ascertain which apps to assess, each app was coded according to purpose. Figure 1 illustrates this process in more detail, including the nature of the excluded apps and provides further descriptive details of the final set of apps included in the analysis including platform and cost. In the 24 cases where apps were available on more than one platform (21 were available on 2 platforms, and 3 were available on 3 platforms) the content was identical. The majority of the apps were free (75.5%), and of those that were paid for, costs were relatively low. One exception was an app aimed at building effectiveness and resilience for the workplace which cost £96 for three months access.

### **3.3 Performance of the app quality assessment tool**

The raters found the tool provided a systematic but time consuming method with which to assess the quality of health behavior change apps (approximately 30 minutes per app). The level of inter-rater agreement was generally high with some exceptions (see Tables 2 and 3). Agreement was low for the question "Does the app focus on initiation of behavior change?" as one rater answered 'yes' only if the focus on initiation was made explicit in the app description. There was a lower level of agreement for question 7, where one rater assumed that apps developed for the 'Change4Life' brand and 'NHS Choices' brand had had health professional involvement, whereas the other rater did not make this assumption. Inter-rater agreement was lower for the question "Is there a publically available manual?". One rater interpreted this to mean a manual aimed at health professionals, whereas the other interpreted it to mean a description of the app. Inter-rater agreement was also low for the question on data protection as one rater answered 'yes' only if the app description made this explicit. These discrepancies were resolved in discussions with a third rater.

### **3.4 Application of the app quality assessment tool**

#### *3.4.1 Theme 1: Purpose of the app*

Table 2 shows the results pertaining to the questions on app purpose. The purpose of all the apps was clear, but in two cases the target behavior was not clearly specified. The likely outcomes were

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specified for most of the apps, although this was unclear in some cases. The majority of the apps focused on the initiation of behavior change, although for several apps this was not obvious.

#### *3.4.2 Theme 2: Planning and development*

In only two cases was it apparent that the app had been developed in collaboration with the target group, and only three of the app descriptions specified that piloting had taken place (Table 2).

Twenty six of the apps had been developed in collaboration with health professionals, but for the remaining apps there was insufficient information to ascertain if this was the case.

#### *3.4.3 Theme 3: Usability*

With regards to app usability (Table 2), there was insufficient information to ascertain if any of the apps incorporated any special features for those with specific needs (such as the ability to change font size or have text read out loud). Six of the apps were 'Information Standards' certified.

#### *3.4.4 Theme 4: Initial Assessment and Tailoring*

Regarding assessment and tailoring (Table 2), most of the apps did collect behavioral data, and although the assessment was subjective, it was felt that all apps were aimed at the right level for the target audience. Only one app assessed users capability to change. Eleven of the apps took some aspects of users' physical, economic and social environment into account. Only one app assessed users motivation to change by asking users to list their motivations for quitting under the headings 'family', 'health' and 'money'. Twenty-six tailored the intervention based on participant responses. There was insufficient information to ascertain if any of the apps targeted users based on a consideration of times in their life when they might be more open to change. Only eleven of the apps carried out a baseline health assessment. Most of these were self-rated assessments, but 'Drinks Meter' did use a recognized alcohol screening test developed by the WHO [24]. Around half of apps employed tailoring based on user progress (either self-rated or objective measures).

#### *3.4.5 Theme 5: Behavior change techniques (BCT)*

With respect to BCT employed, sixteen apps were linked to activities at the population, community or organizational level (Table 2). Sixteen of the apps encouraged users to make environmental changes to support behavior change, and all but one of the apps used a recognized BCT, even if this was just 'shaping knowledge' in the form of information provision. The most popular technique was enablement of self-monitoring (n=41). Over half provided users with feedback on their behavior or its outcomes, and around a third signposted users to relevant services. Twenty one apps facilitated

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access to social support, and six facilitated access to professional support. Twenty four apps encouraged users to agree goals and outcomes, and action plans were used in eighteen. Only one app employed the BCT of prioritising actions in their plans.

#### *3.4.6 Theme 6: Behavioral maintenance and relapse prevention*

Table 3 shows the results for questions regarding behavioral maintenance and relapse prevention. Overall, the apps were not as focussed on maintaining change as they were on initiating it. Twenty one of the apps targeted the maintenance of behavioral change and six addressed relapse. None of the apps encouraged users to consider the achievement of initial goals and then go on to set further ones. Six of the apps had systems in place to try and ensure that feedback and monitoring continued for at least one year and sixteen explicitly encouraged the development of routines.

#### *3.4.7 Theme 7: Evaluation*

Table 3 shows the results for questions about app evaluation. Over half of the apps collected some form of outcome data, but in almost all cases there was insufficient information to ascertain what sort of evaluation processes apps had been subjected to or if there were any plans to do this. As far as we could ascertain, only two apps ('Drink Meter' and Drugs Meter') used validated measures of behavior.

#### *3.4.8 Theme 8: Documentation*

Table 4 illustrates that documentation was lacking in many cases. Although all the apps had a clear description of purpose and content, only two ('Moodkit' and 'Calorie Counter Pro') had a publically available manual. This is perhaps not surprising as apps by their nature should run themselves without needing an operator. The evidence base used was described for fifteen of the apps and the mechanism of action was described at least in rough terms for over half. In thirty six cases it was clear which BCT had been employed, although no acknowledgement was made of the BCT taxonomy [9]. Sixteen of the apps described how they focused on maintenance. There was insufficient evidence to ascertain if documentation would be updated along with app updates. In twenty four cases there was a clear rationale for the BCT employed.

#### *3.4.9 Theme 9: Data protection*

By nature of inclusion in the NHS Apps library, all the apps met data protection requirements.

## **4. Discussion and Conclusion**

#### *4.1 Discussion*

This paper represents the first attempt to apply the NICE behavior change guidance to a sample of mobile apps aimed at health behavior change. The tool was developed to address concerns regarding quality control through a qualitative analysis of the NICE BCG, discussions around relevant aspects to include, and piloting of questions. The tool could be applied by app developers to help ensure their products follow the suggestions in the NICE BCG, by standards organizations wishing to further develop app quality assessment procedures, and by researchers wishing to advance the utility of mobile health apps in clinical settings. The tool helped identify distinctions between the apps, using a framework of nine themes consisting of; purpose, planning, usability, assessment and tailoring, behavior change techniques, maintenance and relapse prevention, evaluation, documentation, and data protection. Overall, the purpose of the apps was clear but there was little evidence for planning and development with the target group or piloting of the apps. There was also a lack of consideration for formal assessment of app usability and evaluation of efficacy of the apps. The apps were generally good at focusing on the initiation of behavior change and around half showed some evidence of tailoring. Despite this there was less of a focus on maintenance and relapse prevention. While all but one of the apps used a recognized BCT, none specifically referred to any specific BCT taxonomy [5-9]. Documentation was poor, with only a small number of apps providing adequate descriptions of the theory behind the behavior change techniques employed.

##### **4.1.2 Study Limitations**

The study has a number of limitations, such as the limited number of apps on which the assessment tool was piloted and the time taken for it to be applied (although this was not systematically measured).

##### **4.1.3 Limitations of the assessment tool**

We considered the potential benefit of adding an unclear category to the assessment tool such as that used in the Cochrane risk of bias assessment [25]. Given that the tool contained a relatively large number of questions, we felt that adding a third outcome category might make it somewhat unwieldy, but future versions might consider this in conjunction with a reduction in the number of questions. The fact that there were some differential interpretations between raters on a number of questions suggests further piloting and discussion was required. A user manual has been developed retrospectively to help clarify what exactly is meant by the questions in the tool (Appendix 2). **This manual may require further piloting and refinement and the authors would welcome the opportunity for future collaborations.**

#### **4.1.4 Alternative approaches**

There are a number of alternative approaches to app quality assessment in development. In the UK, the National Information Board (NIB) is developing a four stage process for app endorsement which will ultimately replace the NHS Health Apps Library [26]. The first stage will consist of an audited online self-assessment process that app developers will be required to work through before their apps are considered for endorsement. The second stage will consist of ‘community evaluation’, using a community of professionals, commissioners and end users. Stage 3 will consist of a more formal assessment of a smaller number of higher quality apps identified in stages one and two. Finally it is envisaged that Stage 4 will consist of an independent impact evaluation, examining efficacy and cost effectiveness. This four stage process will ultimately result in a smaller number of apps being recommended by the NHS than the current system where a large number of apps meeting minimal requirements are included in the library. The app assessment tool we have described in this paper could be adapted to inform the content of the first 3 stages suggested in the proposed NIB approach for app endorsement. This four stage approach could also be informed by the Template for Intervention Description and Replication (TIDieR) checklist [27] which seeks to improve the completeness and reporting of interventions. **The TIDieR checklist was not specifically designed with mobile apps in mind, and while some of the items (such as who delivered the intervention) might not be relevant for this type of intervention, its use would ensure clarity of the content of the apps. “For example, future versions of the tool could address item 5 of the TIDieR checklist (‘Who Provided’) by including a question relating to how the app is delivered in Theme 8 – App documentation. This question should specify that if the app is to be delivered by a third party, their expertise, background and training should be specified. Item 6 of the TIDieR checklist (‘How’) could be incorporated into Theme 3 – App useability, by including a question relating to what platforms and devices the app is compatible with, and Theme 7 – App evaluation, by including a question asking if the device on which the app was delivered will be recorded. Item 7 of the TIDieR checklist (‘Where’) could also be incorporated into Theme 7 – App evaluation, by refining question 43, i.e. ‘Does the app collect data on the location in which the app was accessed?’ Item 8 of the TIDieR checklist (‘When and how’) could also be incorporated by further refining question 43 to ascertain if the app recorded how many times it was accessed by an individual user, and the time and duration of these interactions.**

#### **4.2 Conclusion**

This paper has demonstrated that the NICE (2014) guidance for behavior change interventions can be usefully adapted to form the basis of a quality assessment of mobile apps. The adaptation employed here has provided a structure such a quality analysis and uncovered interesting insights into the nature of apps aimed at health behavior change.

#### **3.2 Practice Implications**

We hope the tool described here will help lay the groundwork for further development of an app quality assessment framework. Although the tool is unlikely to be used by busy clinicians in its current form, it may help stimulate further dialogue between clinicians, app developers, patients, and regulatory bodies. Future work could focus on refining this tool to include user and expert

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opinions, perhaps by incorporating it into the four-stage endorsement process suggested by the NIB. It is hoped that such endeavours will help improve the quality of health behavior change apps available for patients, increase clinician confidence in recommending these apps, clarify a standard for developers to aim for, and help policy makers incorporate such interventions into the wider healthcare service.

## **5. Acknowledgements**

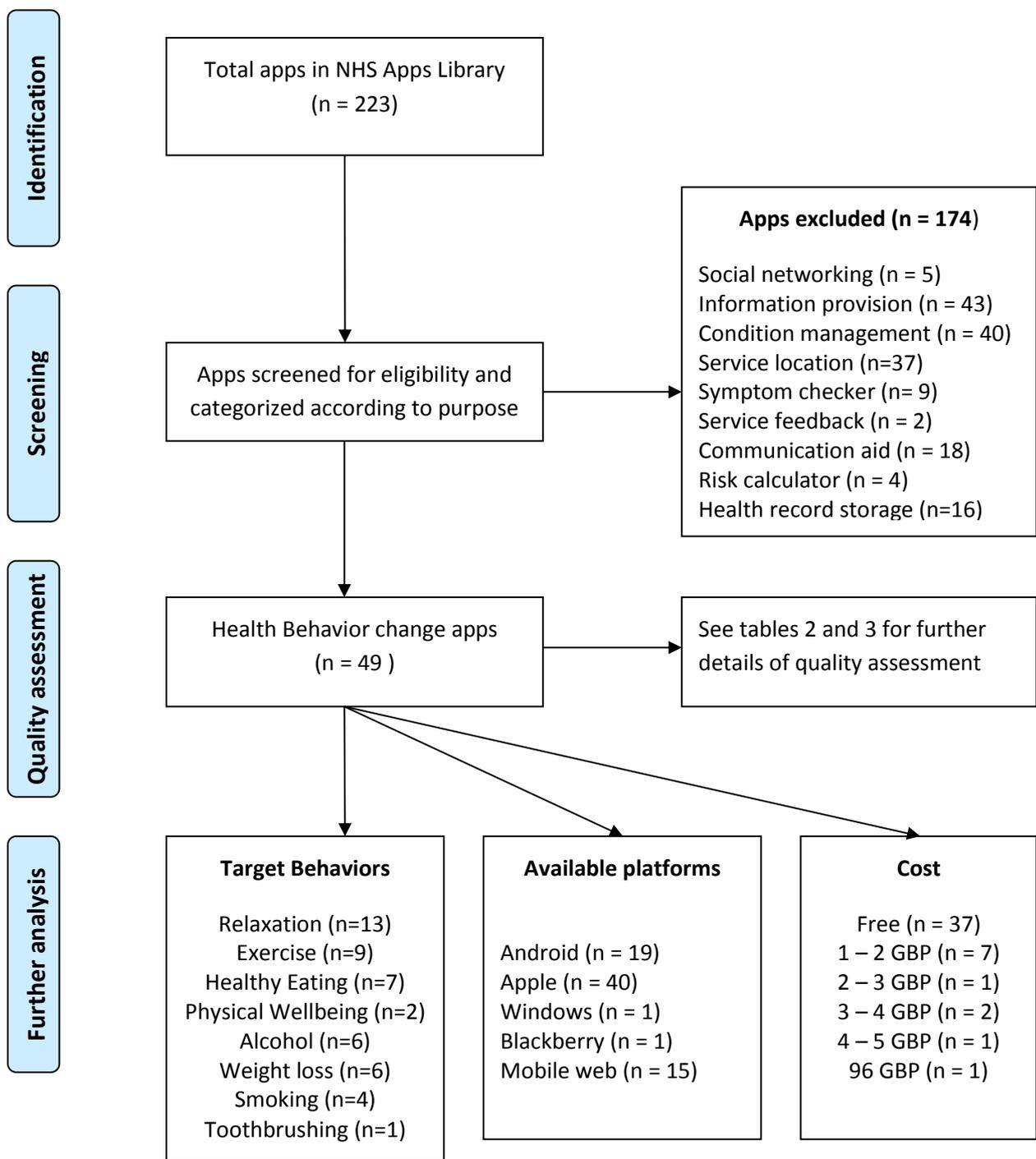
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**Figure 1: Selection of apps from the NHS Apps library and details of the final sample of apps**



**Table 1: Themes relating to app quality extracted from NICE guidance**

<b>Theme</b>	<b>Example question</b>
1. Purpose	Is the target behavior clearly specified?
2. Planning and development	Was the app developed in collaboration with target group?
3. Usability	Does the app have special features for specific needs?
4. Initial assessment and tailoring	Does the app assess users' motivation to change?
5. Behavior change technique	Does the app facilitate access to social support?
6. Maintenance & relapse prevention	Does the app include techniques to address relapse?
7. Evaluation	Will the efficacy of the app be evaluated?
8. Documentation	Is there a publicly available manual for the app?
9. Data Protection	Does the app comply with data protection standards?

**Table 2: App purpose, planning and development, usability, tailoring, and behavior change technique**

Question	Yes (N)	Yes (%)	% Agreement
<b>Theme 1: App Purpose</b>			
1. Is the purpose of the app clear?	49	100.0	100.0
2. Is the target behavior clearly specified?	47	95.9	93.8
3. Are the likely outcomes clearly specified?	43	87.8	75.0
4. Does the app focus on initiation of behavior change?	38	77.6	10.3
<b>Theme 2: Planning and development</b>			
5. Developed in collaboration with target group?	2	4.1	97.9
6. Was the app piloted?	3	6.1	95.9
7. Were health professionals involved in development?	26	53.1	66.7
<b>Theme 3: App usability</b>			
8. Special features for those with specific needs?	0	0.0	100.0
9. Is the app "Information Standards" certified?	6	12.2	100.0
<b>Theme 4: Initial assessment and tailoring</b>			
10. Does the app collect behavioral data?	37	75.5	87.5
11. Aimed at the right level for the target population?	49	100.0	100.0
12. Assess capability to change?	1	2.0	100.0
13. Take account of users' environment?	11	22.4	91.7
14. Assess users' motivation to change?	1	2.0	100.0
15. Tailored intervention based on responses?	26	53.1	83.3
16. Consider times when users more open to change?	0	0.0	100.0
17. Carry out a relevant baseline health assessment?	11	22.4	95.8
18. Is tailoring based on user progress?	12	24.5	87.5
<b>Theme 5: Behavior change technique employed</b>			
19. Links to complementary activities?	16	32.7	83.3
20. Encourage users to make environmental changes?	16	32.7	95.9
21. Use of one or more recognized BCT?	48	98.0	95.9
22. Does the app facilitate access to social support?	21	42.9	91.7
23. Does app facilitate access to professional support?	6	12.2	95.8
24. Does the app signpost to relevant services?	16	32.7	83.3
25. Encourage users to agree goals and outcomes?	24	49.0	97.9
26. Encourage users to develop action plans?	18	36.7	97.9
27. Encourage users to prioritize actions in their plans?	1	2.0	100.0
28. Encourage and support self-monitoring?	41	83.7	100.0
29. Provide feedback on behavior and its outcomes?	29	59.2	83.4

**Table 3: Behavioral maintenance, relapse prevention, app evaluation and documentation**

Question	Yes (N)	Yes (%)	% Agreement
<b>Theme 6: Behavioral maintenance and relapse prevention</b>			
30. Includes focus on maintenance of behavior?	21	42.9	89.5
31. Includes techniques to address relapse?	6	12.2	97.9
32. Consider achievement and future goals and plans?	0	0.0	97.9
33. Regular feedback and monitoring for at least 1 year?	6	12.2	100.0
34. Encourage development of routines?	16	32.7	97.9
<b>Theme 7: App evaluation</b>			
35. Does the app collect outcome data?	29	59.2	97.9
36. Are novel BCTs employed by app to be evaluated?	0	0.0	100.0
37. Collected data available to relevant bodies?	0	0.0	100.0
38. Will the efficacy of the app be evaluated?	3	6.1	97.9
39. Will intervention fidelity be evaluated?	1	2.0	97.9
40. Will the impact on health inequalities be assessed?	0	0.0	100.0
41. Likely to cause harm?	0	0.0	100.0
42. Validated assessment tool to measure behavior?	2	4.0	97.9
43. Uptake and reach of the app assessed?	0	0.0	100.0
44. Adaptation of existing data collection systems?	0	0.0	100.0
45. Evaluation by independent body?	0	0.0	97.9
46. Evaluation planned prior to release of app?	1	2.0	97.9
47. Specialist input for evaluation?	1	2.0	97.9
48. Is a description of the evaluation design available?	2	4.1	100.0
49. Does the evaluation use qualitative tools?	1	2.0	97.9
50. Process and outcomes using objective measures?	2	4.1	100.0
51. Establishment of routine data collection?	0	0.0	100.0
52. Adequate sample sizes for evaluation ensured?	2	4.1	97.9
53. Will outcomes be assessed for over 1 year?	0	0.0	100.0
<b>Theme 8: App documentation</b>			
54. Detailed description of the app publicly available?	49	100.0	95.8
55. Publicly available manual?	2	4.1	37.5
56. Is the evidence base used described?	15	30.6	89.6
57. Is the mechanism of action described?	29	59.2	100.0
58. Is it clear which BCT was employed?	36	73.5	91.7
59. Description how the app addresses maintenance?	16	32.7	89.6
60. Documentation updated along with app updates?	0	0.0	100.0
61. Clear rationale for the BCT employed?	24	49.0	89.6
<b>Theme 9: Data protection</b>			
62. Does app comply with data protection standards?	49	100.0	33.3