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Running head: Diabetes apps with behaviour change techniques

Title: An evaluation of diabetes targeted apps for Android smartphone in relation to behaviour change techniques

Authors:

Charlotte D Hoppe

School of Food Science and Nutrition University of Leeds Leeds LS2 9JT and Department of Nutrition and Dietetics King's College London Franklin-Wilkins Building Stamford Street London SE1 9NH

Janet E Cade

Nutritional Epidemiology Group School of Food Science and Nutrition University of Leeds Leeds LS2 9JT Phone number: 0113 343 6946 Fax number: 0113 343 2982 E-mail address: j.e.cade@leeds.ac.uk

Michelle Carter

Nutritional Epidemiology Group School of Food Science and Nutrition University of Leeds Leeds LS2 9JT

Keywords: diabetes, behaviour change techniques, mobile apps, Smartphone

Details of role in the study: JEC had the initial idea of the study and had a major role in its design and execution, CDH undertook the evaluation of the apps, the statistical analysis and the majority of

drafting the paper and MC contributed to the draft of the paper, reviewed its content and approved the final version for submission.

1 Abstract

BACKGROUND: Mobile applications (apps) could support diabetes management through
 dietary, weight and blood glucose self-monitoring; and promoting behaviour change. This study
 aimed to evaluate diabetes apps for content, functions and behaviour change techniques (BCTs).

METHODS: Diabetes self-management apps for Android smartphones were searched for on
 Google Play Store. Ten apps each from the following search terms were included; 'diabetes',
 'diabetes type 1', 'diabetes type 2', 'gestational diabetes'. Apps were evaluated by being scored
 according to their number of functions and BCTs, price and user rating.

RESULTS: The average number of functions was 8.9 (SD 5.9) out of a possible maximum of 27. Furthermore, the average number of BCTs was 4.4 (SD 2.6) out of a possible maximum of 26. Apps with optimum BCT had significantly more functions (13.8, 95% CI 11.9, 15.9) than apps that did not (4.7, 95% CI 3.2, 6.2; p<0.01) and significantly more BCTs (5.8, 95% CI 4.8, 7.0) than apps without (3.1, 95% CI 2.2, 4.1; p<0.01). Additionally, apps with optimum BCT also cost more than other apps. In the adjusted models, highly rated apps had an average of 4.8 (95% CI 0.9, 8.7; p=0.02) more functions than lower rated apps.

CONCLUSION: 'Diabetes apps' include few functions or BCTs compared to the maximum score possible. Apps with optimum BCTs could indicate higher quality. App developers should consider including both specific functions and BCTs in 'diabetes apps' to make them more helpful. More research is needed to understand components of an effective app for people with diabetes.

21 Introduction

Diabetes mellitus is becoming increasingly prevalent worldwide. Currently, 387 million people are diagnosed with diabetes, representing 8.3% of the global population⁽¹⁾, and this figure is expected to rise to 592 million by the year 2035. Affected individuals have to manage it for the rest of their lives. A number of long term complications are associated with diabetes⁽²⁾, and effective control of blood pressure and blood glucose reduces the risk of both macro-vascular and micro-vascular diseases^(3; 4; 5). It is therefore important to carefully manage the disease to minimise its impact on morbidity and mortality.

In 2015, 76% of the UK population owned a Smartphone⁽⁶⁾, and it is predicted that by 2017, 2.5 30 billion people worldwide will own a Smartphone ⁽⁷⁾. Smartphones therefore have the potential to be 31 used to manage disease using "mHealth" (mobile health) applications⁽⁸⁾. There were over 6,000 32 medical apps available on the Android market in 2013⁽⁹⁾, and this has since nearly quadrupled to 33 23,000 apps⁽¹⁰⁾. Many apps aim to support self-management for people with diabetes, however, while 34 mHealth apps may benefit people suffering from chronic disease, there are also problems associated 35 with them. These problems include lack of evidence on clinical effectiveness, lack of integration into 36 the health care system and potential threats to safety ⁽⁹⁾. A recent study found that health apps in the 37 UK NHS Health Apps Library had poor compliance with data protection principles⁽¹¹⁾. For an app to 38 be recommended to patients by health professionals, its effectiveness should be scientifically proven. 39 Most apps do not have a strong evidence base demonstrating their effectiveness. The US Food and 40 Drug Administration (FDA) defined a mobile app to be a medical device if it was intended to 41 diagnose, cure, mitigate, treat or prevent a disease⁽¹²⁾, needing FDA approval before being released 42 to the market. Unapproved apps could lead to adverse health effects if users substituted a doctor's 43 visit with consulting an $app^{(9)}$. 44

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There is substantial research investigating new technology in the use of managing disease. However, 46 in relation to diabetes-linked conditions, these are mostly focused on weight loss, and look at web-47 based programmes rather than mobile apps^(13; 14). Additionally, these studies have not looked at BCTs, 48 but rather measure BMI (Body Mass Index, kg/m²) or body weight as outcomes. While these are 49 appropriate outcomes to measure effectiveness of diabetes management interventions, it is also 50 important to understand which BCTs are promoting effective behaviour change. Some diabetes 51 management apps have been evaluated, but these were web-based rather than mobile app-based^(16; 17). 52 and measure user satisfaction or usability^(18; 19) rather than BCTs. A qualitative study on usability of 53 apps for weight loss⁽²⁰⁾ concluded that app designers should employ BCTs to improve effectiveness. 54 Furthermore, a Cochrane review⁽²¹⁾ investigated which computer-based intervention would be most 55 effective at improving HbA1c levels in adults with diabetes, and found that mobile apps were more 56 effective than computer programmes used in hospitals or at home. The authors thought that this was 57 due to the inclusion of control theory techniques such as self-regulation. 58

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Twenty six distinct, theory-linked BCTs have been described and tested⁽²²⁾. BCTs are theory-based methods to facilitate change in individuals, and examples include 'Prompt intention formation' and 'Model or demonstrate behaviour' which could be incorporated into mobile apps. A meta-analysis⁽²³⁾ was undertaken to assess the effectiveness of these 26 BCTs in promoting physical activity and healthy eating. It found that interventions that combined self-monitoring with at least one other technique derived from control theory were significantly more effective than the other interventions. The aim of this study was to evaluate Android apps for people with diabetes in terms of which functions they included and which BCTs they employed to encourage behaviour change. To our knowledge there is no research assessing the inclusion of BCTs in interventions used in diabetes mobile apps. This research could provide a basis for improving 'diabetes apps' in the future.

70 Methods

71 App selection

Google Play Store (UK) for Android was used as a database to search for relevant apps on 27 October 72 2014. Since there is no existing appropriate category, these specific search terms were used: 73 'diabetes', 'diabetes type 1', 'diabetes type 2' and 'gestational diabetes'. The apps were initially pre-74 screened for suitability before being downloaded. Inclusion criteria were 1) to be intended for patients 75 with type 1, 2 or gestational diabetes, 2) to be addressing any aspect of management of diabetes (e.g. 76 blood glucose monitoring, medication, healthy diet), 3) to have stand-alone functionality (i.e. not 77 requiring membership in a specific programme or website to function) and 4) to be in English. The 78 exclusion criteria were 1) to be for self-diagnosis for the user and 2) to be intended for education of 79 medical personnel. Apps that did not function properly on the test phone, for example, they would 80 not open or we could not get past the introduction screen, were also excluded. This pre-screening was 81 based on the app descriptions and screenshots provided in Google Play Store. The number of medical 82 apps available on Google Play Store is 23,000⁽¹⁰⁾ with only a small proportion of these of relevance 83 to people with diabetes. The exact number of 'diabetes apps' could not be determined as Google Play 84 Store does not state the number of search results. Each search only shows 200 app results. Due to 85 restraints in time and resources, the number of apps included had to be restricted. The first ten apps 86 passing the pre-screening from each search term were included, giving 40 apps in total. App ranking 87 is partly determined by App Store Optimisation, which among other aspects takes into account 88 keyword alignment (i.e. how the user's search term matches with words in the app title and 89 description), and app performance (e.g. app ratings and number of downloads)⁽²⁴⁾. An algorithm is 90 used to determine the exact ranking, and this is not available to the general public, and undergoes 91 continuous change⁽²⁵⁾. For the purposes of this study it is therefore not possible to find out the total 92 number and ranking of all available diabetes-related apps. 93

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Following identification, the apps were downloaded and evaluated again based on the same inclusion and exclusion criteria as stated above. At this point some of the apps were excluded, and therefore a second stage of searches and screening was performed to meet the study's aim of evaluating 40 apps, ten from each search term (Figure 1). This second search was performed on 9 June 2015. Five apps
 were independently evaluated by another assessor in order to determine the repeatability and relative

- validity of the assessments.
- 101

102 App testing

Each app that met the inclusion and exclusion criteria was used by the author (CH) to identify the 103 functions and BCTs included. The results were recorded in a data extraction form (Table 4) recording 104 the functions and BCTs included in each app. A possible 27 functions were categorised into 105 'Provision of information', 'Allows self-recording', 'Generates output from self-recording', 'Data 106 management' and 'Other'. The 26 BCTs identified by Michie and Abraham⁽²²⁾, were categorised into 107 'Motivation enhancing', 'Planning and preparation' and 'Goal striving and persistence' (see a list of 108 these in **Figures 2-3**). Therefore, a maximum score of 53 could be obtained by each app. Each app 109 was downloaded immediately before assessment using the author's private mobile phone. The 110 majority of apps were evaluated between the 3 November and 10 December 2014, and apps identified 111 in the second search stage were evaluated between the 9 June and 15 June 2015. Some apps had data 112 collection functions, such as recording blood glucose readings or food intake, and where this was the 113 case, they were used for two days to give sufficient data for graph generation. Apps which did not 114 have data collection functions were explored to extract information on all other functions and BCTs 115 present. 116

Based on the meta-analysis by Michie et al. found ⁽²³⁾, the most effective combination of BCTs is 'Prompt self-monitoring of behaviour' in combination with at least one of four other self-regulatory techniques: 'Prompt intention formation', 'Prompt specific goal setting', 'Provide feedback on performance' and 'Prompt review of behavioural goals'. This was evaluated as 'optimum BCT' in this study'.

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123 Statistical analysis

The results were analysed using the statistical software Stata/IC (Release 13.1; Stata Corp, College Station, TX). T-tests were performed to assess the difference in mean number of functions, number of BCTs, overall score, price and user rating according to inclusion of 'optimum BCT', price (free or paid) and user rating. For the latter, user rating, normally ranging from one to five, was divided into the following two groups; low=1.0-4.0 and high=4.1-5.0. The uneven division of user rating was due to average app rating for the majority of apps being greater than 4. Regression was performed to see if there was a relationship between number of functions, number of BCTs and overall score versus price (£) and user rating. Regression models for price adjusted for user rating and vice versa. Cohen's
 kappa was calculated to determine the inter-rater reliability from the duplicate extracted data.

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134 **Results**

App selection

The initial pre-screening gave a list of 40 apps to be further evaluated for eligibility. Of these, 13 apps were excluded due to non-conformity with inclusion criteria (**Figure 1**). The excluded apps were either intended for training of health personnel (n=2), no longer available at the point of download (n=5), required the use of a website along with the app (n=2), non-functional (n=1), not in English (n=1) or not for previously diagnosed patients (n=2). This initially gave 27 apps to be included in the study. However, to improve the generalisability of the study, 13 further apps were added from a repeated search to give 40 apps in total. These were individually pre-screened before inclusion.

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144 App testing

Based on overall score (i.e. the sum of number of functions and BCTs), Diabetes Tracker by Mig 145 Super, Diabetes: M by Rossen Varbanov and Diabetes Companion by mySugr GmbH ranked highest, 146 scoring 29, 27 and 26 out of 53 respectively. These were all apps that offered recording of various 147 physical measures, e.g. blood glucose, weight and height. They all included 'optimum BCT'. The 148 apps scoring lowest overall were Type 1 Diabetes by Colby Taylor, Recipes for Diabetes by 149 University of Illinois Extension and Diabetic Diet Samples by Awesomeappcenter LLC, with scores 150 of 2, 3 and 4 and out of 53 respectively. These apps focused on giving information and advice about 151 the disease and how to manage it. The average overall score was 13.2 (standard deviation (SD) 7.4) 152 out of 53 (Table 3). 153

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¹⁵⁵ The average number of functions included in the apps was 8.9 (SD 5.9) out of 27 (**Table 3**).

The most common functions were 'Enter blood glucose values' and 'Export data to Smartphone/send 156 data', which were included in 23 and 22 of the apps respectively. This involved downloading data or 157 graphs to the Smartphone directly; sending it to a specified email address; or uploading it to a cloud 158 based storage system. Other common functions included enter medication; weight; carbohydrates 159 consumed. Thirty-two out of the 40 apps included 'Any other (describe)', a mixed group of functions 160 including anything that was not included in the rest of the list. These ranged from offering a forum to 161 communicate with other people with diabetes; a game including a point system for doing beneficial 162 activity; making a shopping list for meals; and information on which McDonald's meals were 163 'diabetic-friendly', and few were found in more than one app. Only one app included the potential to 164

¹⁶⁵ generate a table of nutrients consumed. None of the apps included 'Technological additional feature:

- ¹⁶⁶ Connect glucose meter to Smartphone to transfer data' (**Figure 2**).
- 167

The inclusion of BCTs in apps was far less common than the inclusion of functions. The average 168 number of BCTs was 4.4 (SD 2.7) out of 26 (Table 3). The most commonly included technique was 169 'Prompt self-monitoring of behaviour' (n=23) and 'Prompt intention formation' (n=20). These 170 techniques are both among the self-regulatory techniques which were identified as most effective 171 when used in combination with each other⁽²³⁾. However, fewer apps (n=18) had 'optimum BCT' 172 defined as 'Prompt self-monitoring of behaviour' with at least one other self-regulatory technique 173 (i.e. 'optimum BCT' 'Prompt intention formation', 'Prompt specific goal setting', 'Provide feedback 174 on performance' and 'Prompt review of behavioural goals'). Five BCTs were not used in any of the 175 apps: 'Prompt barrier identification', 'Agree on behavioural contract', 'Prompt practice', 'Prompt 176 self-talk', and 'Motivational interviewing' (Figure 3). 177

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App characteristics

Apps including 'optimum BCT' had more functions (13.8, 95% CI 11.9, 15.9) than apps that did not 180 (4.7, 95% CI 3.2, 6.2; p<0.01). This was also true in all the subgroups of functions. The same was 181 found to be true with regard to the BCTs themselves, with more BCTs (5.8, 95% CI 4.8, 7.0) in apps 182 with 'optimum BCT' than in apps without (3.1, 95% CI 2.2, 4.1; p<0.01). Logically, apps with 183 'optimum BCT' also had an overall higher score (19.8, 95% CI 17.1, 22.5) than those that did not 184 have 'optimum BCT' (7.9, 95% CI 6.3, 9.4; p<0.01). Furthermore, apps with 'optimum BCT' had a 185 higher price (in £) (3.2, 95% CI 0.6, 5.9) than those without (0.3, 95% CI -0.0, 0.5; p=0.01) (Table 186 1). 187

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Apps with a high user rating had more functions (10.6, 95% CI 8.3, 13.9) than those that had a low 189 rating (6.2, 3.0, 9.5; p=0.03). This was also true for the functions subgroups, except 'Other'. 190 Conversely, the number of BCTs included was not related to user rating (high user rating number of 191 BCTs 4.5, 95% CI 2.8, 6.1) vs. (low user rating number of BCTs 4.5, 95% CI 3.6, 5.3; p=0.98). Only 192 BCTs in the subgroup 'Goal striving and persistence' were significantly more common in highly rated 193 apps (2.7, 95% CI 2.0, 3.4) compared to low user rated apps (1.5, 95% CI 0.4, 2.6; p=0.05). However, 194 there was an indication of a higher user rating in apps with 'optimum BCT' (4.4, 95% CI 4.2, 4.5) 195 than in those without (4.0, 95% CI 3.6, 4.4; p=0.07) (**Table 1**). 196

The regression analysis also resulted in a significant association between number of functions, but not BCTs, and user rating (**Table 2**). In the adjusted models, highly rated apps had an average of 4.8 (95% CI 0.9, 8.7; p=0.02) more functions than lower rated apps. However, payment for an app was significantly related to higher number of BCTs; paid apps had a higher number of BCTs by 1.9 (95% CI 0.1, 3.8; p=0.04) than free ones. Price did not affect the overall score, but user rating was associated with overall score. Highly rated apps had a higher overall score by 5.1 (95% CI 0.1, 10.0; p=0.04).

The inter-rater reliability gave an average agreement of 86% and kappa was 0.68, corresponding to a substantial or good agreement between raters.

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208 Discussion

The inclusion of 'optimum BCT' has been used as a proxy for app quality, because this combination 209 of BCTs is most effective at changing behaviour⁽²³⁾ and is therefore potentially most beneficial to a 210 person with diabetes using the app. The analysis showed that both the number of functions and the 211 number of BCTs included in the apps were quite low. The average number of BCTs was only 4.4 (SD 212 2.6) out of 26. Therefore, BCTs were probably not actively considered in the development of the 213 apps. Diabetes is a chronic disease requiring lifelong management; changing behaviour is key to 214 achieving this successfully⁽²⁶⁾. The combination of BCTs that was found to be most effective⁽²³⁾, was 215 only included in 18 of the 40 apps. It is clear that there is still considerable potential for improvement 216 of BCT inclusion in 'diabetes apps'. 217

218

Apps with optimum BCT had significantly more functions and BCTs, indicating that these could be 219 predictors of app quality. Furthermore, user rating significantly predicted the number of functions 220 included; whereas price was linked to increased number of BCTs. There was a non-statistically 221 significant suggestion of a higher user rating in apps with 'optimum BCT' compared to apps without 222 the optimum combination of BCTs. The validity of user rating as a predictor of app effectiveness is 223 uncertain, as most users are unlikely to base their rating on whether they managed to change 224 behaviour. Research on user reviews⁽²⁷⁾ found that the most common causes of complaint were among 225 others attractiveness, stability and compatibility. None of the causes listed were related to the apps' 226 ability to change behaviour. Apps with 'Optimum BCT' cost more than others. West et al.⁽²⁹⁾, who 227 appraised a number of apps based on their potential to influence behaviour change found that more 228 expensive apps were more likely to be scored as intending to promote health or prevent disease. 229

The small sample size of the study, only 40 apps were evaluated, could have limited our ability to 231 determine predictors of app quality. With approximately $23,000^{(10)}$ health apps available, the total 232 number of 'diabetes apps' is likely to be much greater than 40 and the sample size therefore presents 233 a limitation to this study. Additionally, iTunes Store was not searched for apps, and there is a 234 possibility that there are some key diabetes management apps which were therefore missed. We did 235 however undertake independent evaluation of a subsample of the apps included and found good 236 agreement between reviewers. Resource implications precluded duplicate extraction of all apps, 237 which is another limitation of this study. 238

239

Diabetes Tracker by Mig Super, which scored highest in this study, is an app that includes recording 240 of blood glucose, carbohydrate consumption and activity, as well as providing tips for recipes and 241 physical exercises, dietary guidelines for each type of diabetes and information on so-called 242 'superfoods'. The app that scored lowest, Type 1 Diabetes by Colby Taylor included different types 243 of functions. They were more informative and advisory; giving rather limited information about the 244 condition and about healthy meals that could keep blood sugar levels stable. It is clear that apps 245 directed at people with diabetes include a range of different functions, making comparisons between 246 them challenging. This variation in intended use creates a heterogeneity which might impact on the 247 results. 248

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As previously mentioned, there were five BCTs that were not included in any app. It might be 250 unrealistic to think that all of the BCTs can feasibly be fitted into a mobile phone app. Some 251 techniques would be more challenging to include since there was no link to a human decision maker, 252 e.g. deciding when the target behaviour has been reached, or if the participant has relapsed. Peer or 253 health care professional support would be possible through links to social media or downloads to 254 surgery records. 'Agree on behavioural contract' could have been included in an app, for instance as 255 behavioural goals written by the user themselves within the app or for the user to agree to pre-written 256 goals. 257

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The function 'Connect glucose meter to Smartphone to transfer data' was not included in any apps. The list of possible functions was developed by the author, partly based on similar research done by Chen⁽³⁰⁾ as well as knowledge about which elements are important when managing diabetes. However, expecting the inclusion of this function is not unreasonable. There are 'diabetes apps' currently on the market, not identified by our search which do have the possibility of being connected to a blood glucose meter either via a USB cable (e.g. Apps Glooko by Glooko and iBGstar by Sanofi Diabetes) or wirelessly via Bluetooth (e.g. iHealth Gluco-Smart by iHealth Lab Inc.), and thereby transferring glucose readings directly to the diabetes management app. This is a great advantage to the user because it eliminates the burden of manually entering blood glucose values into the app.

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As briefly mentioned previously, one app included a game where the user could earn points for 269 undertaking health behaviours (Diabetes Companion by mySugr GmbH). Gamification is a term 270 describing the use of game elements in a non-game setting⁽³¹⁾. There is some evidence that 271 gamification is useful in the management of diabetes^(31; 32), and Diabetes Companion is also one of 272 the highest scoring apps in this study, possibly due to greater facilitation of some BCTs. Similarly, 273 social support has repeatedly been shown to have a beneficial effect on diabetes management^{(33),(34)}, 274 but only nine out of the 40 apps provided at forum for the users to communicate among each other 275 ('Link to social media'). Again, this aspect could be worth including in a 'diabetes app' in order to 276 improve outcomes for the user. 277

A weakness of this study is that it did not measure actual behaviour change as an outcome. Instead, 278 the inclusion of specific BCTs was used as a proxy for effectiveness⁽²³⁾. The optimum BCT score was 279 derived from a peer reviewed meta-analysis including 122 papers. Although this was not focussed on 280 diabetes management, but on diet and physical activity, these are both factors important in the 281 management of type 2 diabetes. More recent evidence, published after the main part of the present 282 study was conducted is conflicting. Avery et al. conducted a meta-analysis to determine which BCTs 283 were most effective at increasing levels of physical activity, and consequently improving HbA1c 284 levels in adults with diabetes type $2^{(35)}$. The four most effective techniques they found were 'Prompt 285 focus on past success', 'Barrier identification/problem-solving', 'Use of follow-up prompts' and 286 'Provide information on where and when to perform physical activity'. 'Prompt focus on past success 287 could be perceived as included within 'self-monitoring of behaviour' provided that this behaviour 288 was indeed a success. Apart from that, the techniques found to be most effective differed completely. 289 This suggests that finding BCTs that can be generalised to behaviour change interventions is difficult 290 and may be behaviour or condition specific. Future work may include different interpretations of the 291 most effective BCTs or undertaking a randomised controlled trial of apps including measurement of 292 behaviour change as an outcome. 293

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The aim of this study was to evaluate 'diabetes apps' with regard to behaviour change techniques. The same taxonomy of BCTs has previously been used in relation to mobile apps for physical activity and diet⁽³⁶⁾. However, we believe this is the first study looking at BCTs in 'diabetes apps'. The mobile app market is quickly changing and can be perceived as rather chaotic⁽³⁷⁾. Health apps that have not 310

been approved by a professional body may be problematic if users are not instructed correctly. The 299 European Directory of Health Apps (2012) reviewed about 200 health apps in cooperation with 300 patient groups⁽³⁸⁾. The 'diabetes apps' included that overlapped with the apps evaluated here were 301 Carbs & Cals by Chello Publishing, Diabetes UK Tracker by Diabetes UK, Glucose Buddy by 302 Azumio, Inc. and OnTrack Diabetes by Medivo. The Directory did not quantitatively evaluate the 303 apps; included apps were recommended by patient groups. These four apps ranked within the upper 304 half of the apps evaluated in the present study. Demidowich et al. assessed 42 'diabetes apps' in 305 2011⁽¹⁹⁾, though they did not include BCTs. Their highest ranking apps were Glucool Diabetes, 306 OnTrack Diabetes, Dbees and Track3 Diabetes Planner. This agrees with the results from the present 307 study which also evaluated Glucool Diabetes by 3qubits and OnTrack Diabetes by Medivo, ranking 308 them seventh and eighth overall. 309

In conclusion, we have conducted a study evaluating diabetes self-management apps with regard to 311 BCTs. This is highly relevant in today's society as both Smartphone usage and diabetes is becoming 312 increasingly prevalent. Behaviour change is an essential aspect of successful diabetes management, 313 and incorporating BCTs in 'diabetes apps' is a great opportunity to provide people with diabetes with 314 a self-management tool. However, the 'diabetes apps' on the Android market were found to generally 315 include few functions and even fewer BCTs. The three apps scoring most highly in this study were 316 Diabetes Tracker by Mig Super, Diabetes: M by Rossen Varbanov and Diabetes Companion by 317 mySugr GmbH, these had the most functions and BCTs and including the combination of BCTs 318 thought to be most effective at changing behaviour. Health professionals may want to recommend 319 these apps to people with diabetes. More research on the effectiveness of BCTs in mobile apps is 320 needed, this time with more tangible outcomes of behaviour change techniques, for instance HbA1c 321 levels or weight change. With effectiveness established, app developers could work in conjunction 322 with doctors, dietitians and psychologists, who have expert knowledge in the field, to include more 323 BCTs in apps and make them as beneficial to the patients as possible. 324

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328

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329 Conflict of interest

This work was carried out without external funding and no competing financial interests exist. JEC

and MC have developed a smartphone app My Meal Mate which aims to support weight loss.

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