

4-1-2022

A pilot sequential multiple assignment randomized trial (SMART) protocol for developing an adaptive coaching intervention around a mobile application for athletes to improve carbohydrate periodization behavior

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[10.1016/j.conctc.2022.100899](https://doi.org/10.1016/j.conctc.2022.100899)

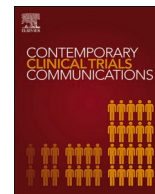
Yan, X., Dunne, D. M., Impey, S. G., Cunniffe, B., Lefevre, C. E., Mazorra, R., ... & Chakraborty, B. (2022). A pilot sequential multiple assignment randomized trial (SMART) protocol for developing an adaptive coaching intervention around a mobile application for athletes to improve carbohydrate periodization behavior. *Contemporary Clinical Trials Communications*, 100899. <https://doi.org/10.1016/j.conctc.2022.100899>

This Journal Article is posted at Research Online.

<https://ro.ecu.edu.au/ecuworks2022-2026/237>

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ARTICLE INFO

Keywords:

Mobile application
Athletes
Carbohydrate periodization
Behavioral sciences
Adaptive interventions
Sequential multiple assignment randomized trial

ABSTRACT

Background: It has recently been identified that manipulating carbohydrate availability around exercise activity can enhance training-induced metabolic adaptations. Despite this approach being accepted in the athletic populations, athletes do not systematically follow the guidelines. Digital environments appear to allow nutritionists to deliver this intervention at scale, reducing expensive human coaching time. Yet, digitally delivered dietary behavior change interventions for athletes and the coaching strategy to support them are still novel concepts within sports nutrition.

Methods/design: We aim to recruit 900 athletes across the UK. 500 athletes will be recruited to test the feasibility of a novel menu planner mobile application with coaching for 6 weeks. 250 athletes with pre-existing nutritionist support will also be recruited as control. We will then conduct a 4-week pilot sequential multiple assignment randomized trial (SMART) with an additional 150 athletes. In the SMART, athletes will be given the application and additional coaching according to their engagement responses. The primary outcomes are the mobile application and coach uptake, retention, engagement, and success in attaining carbohydrate periodization behavior. Secondary outcomes are changes in goal, weight, carbohydrate periodization self-efficacy, and beliefs about consequences. Due to the high attrition nature of digital interventions, all quantitative analyses will be carried out based on both the intention-to-treat and per-protocol principles.

Discussion: This study will be the first to investigate improving carbohydrate periodization using a digital approach and tailored coaching strategies under this context. Foundational evidence from this study will provide insights into the feasibility of the digital approach.

1. Introduction

Sports nutrition has long been aware of the benefits of carbohydrates when it comes to exercise performance [1,2]. However, more recently it has been identified that manipulating carbohydrate availability to strategically undertake specific training sessions with higher – and

where appropriate lower – carbohydrate availability maintains metabolic flexibility, enhancing training-induced adaptations [3,4]. As a result, a “fuel for the work required” theoretical framework was developed [5]. This framework postulates that the provision of nutrition, with a focus on carbohydrate, should be tailored to the individual based on the exercise they undertake, and the time available for recovery, to optimize the desired training or performance response. This has since

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<https://doi.org/10.1016/j.conctc.2022.100899>

Received 13 March 2021; Received in revised form 23 December 2021; Accepted 30 January 2022

Available online 1 February 2022

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Abbreviations:	
App:	custom-built native menu planner mobile application
NC	nutrition coaching
SMART	sequential multiple assignment randomized trial

been recognized and accepted as an applied intervention strategy in the field of sports nutrition [5–8]. Yet, despite athletes knowing how to periodize carbohydrate and energy intake, they do not systematically follow current sports nutrition guidelines [9,10]. Heikura et al. [9] report that athletes struggled to stick to this dietary periodization behavior and highlight that the support required from a practitioner is highly personalized, and as a result time-consuming.

This gap between knowledge and behavior is not new as athletes continue to struggle to adhere despite knowing what and when to eat [11,12]. This may be due to sports nutritionists' lack of formal behavior change training, or the time required to develop such an intervention [13]. In addition to practitioner challenges, Bentley et al. [12] identified a lack of food planning skills as a barrier to nutritional adherence in athletes, linking it to lower levels of motivation. Notably, the authors suggested that athletes need to develop not only the capability to plan, but also be presented with repeated opportunities to practice planning. Given practitioner's time and resource constraints and the fact that food choice is a dynamic, complex, and continually changing process, it appears technology may be well placed to offer a continuous and scalable solution for both parties [14,15].

To date, technology-enabled interventions in nutrition are positively associated with changes in diet [16–19]. It follows then, that digital environments may provide sports nutritionists opportunities to deliver behavior change interventions that can better support the needs of athletes, as well as have the potential to save practitioner time. As a result, we developed a theoretically driven digital menu planner mobile application to enable athletes to plan their food intake in line with their training and competition. However, to date, no research has explored the effectiveness of such a digital tool in sports nutrition.

The first objective of this study is to assess the feasibility of using the custom-built, native menu planner mobile application supported by nutrition coaching in improving carbohydrate periodization behavior. The second objective is to assess the feasibility of strategically timing

human nutrition coaching around the mobile application to improve its effectiveness. Secondary aims include assessing other related health and behavioral outcomes such as weight, goal, change in carbohydrate periodization self-efficacy, and belief about consequences. Exploratory aims include assessing the impact of personality and need for autonomy on application usage, and the potential cost-effectiveness of the approach. The feasibility of the study is defined by the uptake of the mobile application and nutrition coaching, participants' retention and engagement to the application, successful characterization of carbohydrate periodization behavior, and identification of suitable strategy (ies) proposed for the second objective. The findings from this study will help to further refine the application and inform the next steps to the identified strategy (ies) (e.g., a confirmatory trial).

2. Methods

2.1. Research design

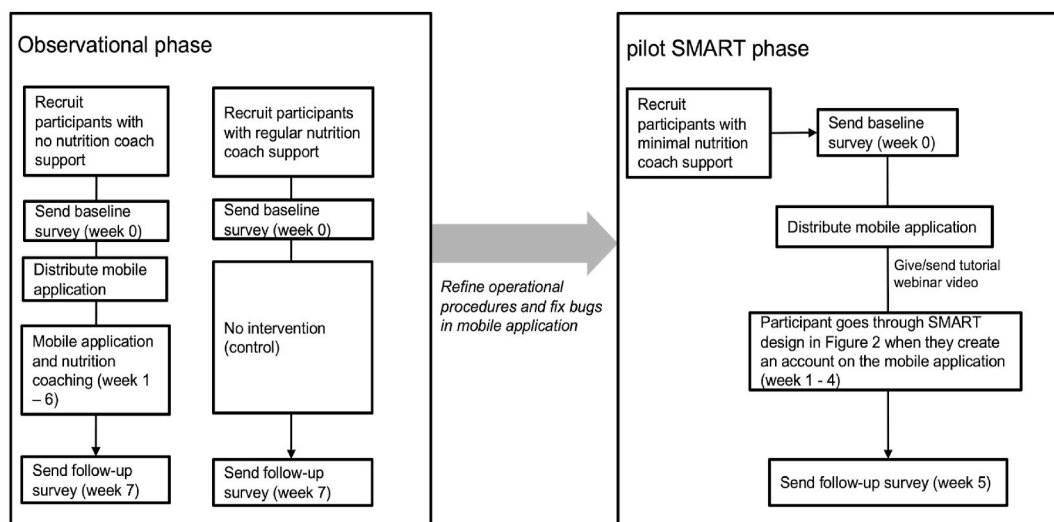
This study will be conducted in two phases, the observational and pilot SMART phases. The flow process of this study is detailed in Fig. 1.

2.1.1. Observational phase

To assess the feasibility of the menu planner mobile application paired with nutrition coaching, an observational study will be carried out with participants using the application and usual nutrition coaching (see interventions below) for 6 weeks. A separate group of participants (with regular pre-existing nutritionist support) will be recruited as control where no intervention will be given. The operational aspects, including participation recruitment via gatekeepers, dissemination, and uptake of the apps, communication channels will also be assessed as part of feasibility. Operational procedures such as email communications and mobile application dissemination (see Appendix Table A.1 for details) will be refined as needed, and any bugs in the mobile application will also be fixed prior to the pilot SMART phase.

2.1.2. Pilot SMART phase

Subsequently, a 4-week pilot sequential multiple assignment randomized trial (SMART) will be carried out on new participants to gain a better understanding and develop possible adaptive coaching intervention strategies around the mobile application. An adaptive intervention strategy is a sequence of decision rules that specify when, how, and what intervention to offer based on the present and past information. The



*All participants are recruited from sports and training organizations. Eligibility were checked by the organizations' gatekeepers before sending the baseline surveys.

Fig. 1. General flow process of the whole study.

SMART is an efficient experimental approach suitable for developing such adaptive intervention strategies, especially when there is not enough a priori information on what sequence, when, and how the intervention components within an adaptive intervention strategy should be tailored [20,21]. In this study's context, the SMART design is used to explore when the human nutrition coaching should be assigned and, when it can be stopped, given the mobile application. From here on, we refer to the adaptive coaching intervention strategies in the SMART design as "strategies".

In this three-stage SMART design, as shown in Fig. 2, all participants will receive the menu planner mobile application (App) at baseline. Participants will be randomized at baseline to determine if they will follow relaxed or stringent response criteria at two time points, the end of week 1 and week 2, for re-randomization. Participants following the relaxed response criteria (all the pathways starting with subgroup A in Fig. 2), will be classified as responders if they engage with the App at least once at the end of week 1 (i.e., $e_1 \geq 1$). Responders will continue with the App only (subgroup G), while non-responders will be re-randomized to either continue with the App only (subgroup C; note subgroups G and C receives the same intervention) or App and nutrition coaching (App + NC) (subgroup D) for one week. At the end of week 2, participants will be re-classified again based on their weekly App engagement (e_2). If participants have $e_2 \geq 2$, they will receive App only (subgroups G1, C1, and D1), else they will be re-randomized again to either receive App (subgroups G2, C2, D2) or App + NC (subgroups G3, C3, D3) at weeks 3–4. Participants following the stringent response criteria (all the pathways starting with subgroup B) follow the same structure, except participants will only be classified as responders when $e_1 \geq 2$ and $e_2 \geq 3$.

It is important to highlight that although the participants may receive the same intervention at a given time-point, the pathways experienced by the participants are different. For example, for participants following the relaxed response criteria and receiving the App at

weeks 3–4, subgroup G1 consists of participants who were consistently responders at both time-points (i.e., $e_1 \geq 1$ and $e_2 \geq 2$) and received the App only in weeks 1 and 2 (see the example pathway highlighted in Fig. 2); subgroup C1 consists of participants who were initially a non-responder then a responder (i.e., $e_1 = 0$ and $e_2 \geq 2$) but also received the App only in weeks 1 and 2; subgroup D1 consists of participants who were initially a non-responder then a responder (i.e., $e_1 = 0$ and $e_2 \geq 2$) and they received App + NC at week 2. By going through all the 18 possible design pathways in Fig. 2, data for a total of 16 embedded strategies may be constructed. We present the corresponding mathematical expressions of the 16 embedded strategies in Table 1. Note that we did not simplify the mathematical expressions in Table 1, to better correspond with Fig. 2. To further facilitate the comprehension of these strategies, we take strategy 7 (also corresponding to the highlighted strategy in Fig. 2) as an example. Strategy 7 can be described as "Use the relaxed response criteria. First, give App in week 1, if the participant has an engagement of ≥ 1 , the participant is a responder and continues with App, else give App + NC in week 2. If the participant has an engagement of ≥ 2 in week 2, give App in weeks 3–4 regardless of the initial response status. If the participant has an engagement of < 2 in week 2, give App if the participant was initially a responder, else give App + NC in weeks 3–4." It is worth pointing out that the 16 strategies primarily explore giving or not giving (App + NC) at different time-points and under different response criteria, thereby exploring the second objective on strategically timing human nutrition coaching around the application.

2.2. Description of the interventions

2.2.1. Menu planner mobile application (app)

The menu planner mobile application (App) is a custom-built native application that is operable on either Android or iOS devices. The custom-built app features were constructed using the Behavior Change Wheel and Atkins and Michie's six-step approach to dietary behavior

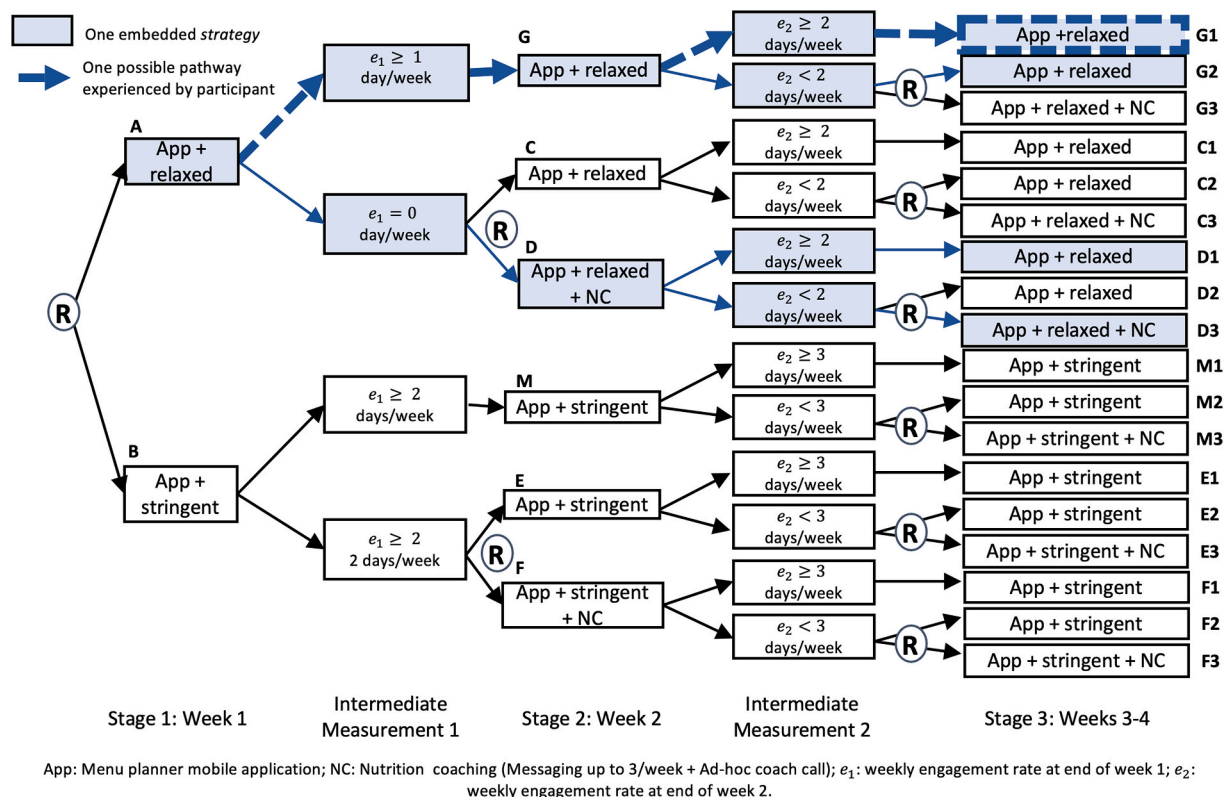


Fig. 2. The SMART design. The highlighted intervention pathway is an example of one of the 16 possible embedded strategies and the dashed arrow is one of the 18 possible pathways (C1-G3 and M1-M3) a participant may go through.

Table 1

The 16 embedded strategies (in mathematical expressions) in the pilot SMART phase, where the relaxed response criteria have responders as ($e_1 \geq 1$ day/week and $e_2 \geq 2$ days/week), and stringent response criteria as ($e_1 \geq 2$ days/week and $e_2 \geq 3$ days/week).

Embedded Strategies	Response Criteria	Intervention at week 1 (Stage 1)	Intervention at week 2 (stage 2)	Intervention at weeks 3–4 (Stage 3)	Subgroups involve at stages 1, 2 and 3
1	Relaxed	App	$App^{e_1 \geq 1} App^{e_1 = 0}$	$App^{e_1 \geq 1} (App^{e_2 \geq 2} App^{e_2 < 2}) App^{e_1 = 0} (App^{e_2 \geq 2} App^{e_2 < 2})$	A, {G, C}, {G1, G2, C1, C2}
2				$App^{e_1 \geq 1} (App^{e_2 \geq 2} (App + NC)^{e_2 < 2})$ $App^{e_1 = 0} (App^{e_2 \geq 2} App^{e_2 < 2})$	A, {G, C}, {G1, G3, C1, C2}
3				$App^{e_1 \geq 1} (App^{e_2 \geq 2} App^{e_2 < 2})$ $App^{e_1 = 0} (App^{e_2 \geq 2} (App + NC)^{e_2 < 2})$	A, {G, C}, {G1, G2, C1, C3}
4				$App^{e_1 \geq 1} (App^{e_2 \geq 2} (App + NC)^{e_2 < 2})$ $App^{e_1 = 0} (App^{e_2 \geq 2} (App + NC)^{e_2 < 2})$	A, {G, C}, {G1, G3, C1, C3}
5			$App^{e_1 \geq 1} (App + NC)^{e_1 = 0}$	$App^{e_1 \geq 1} (App^{e_2 \geq 2} App^{e_2 < 2})$ $(App + NC)^{e_1 = 0} (App^{e_2 \geq 2} App^{e_2 < 2})$	A, {G, D}, {G1, G2, D1, D2}
6				$App^{e_1 \geq 1} (App^{e_2 \geq 2} (App + NC)^{e_2 < 2})$ $(App + NC)^{e_1 = 0} (App^{e_2 \geq 2} App^{e_2 < 2})$	A, {G, D}, {G1, G3, D1, D2}
7				$App^{e_1 \geq 1} (App^{e_2 \geq 2} App^{e_2 < 2})$ $(App + NC)^{e_1 = 0} (App^{e_2 \geq 2} (App + NC)^{e_2 < 2})$	A, {G, D}, {G1, G2, D1, D3}
8				$App^{e_1 \geq 1} (App^{e_2 \geq 2} (App + NC)^{e_2 < 2})$ $(App + NC)^{e_1 = 0} (App^{e_2 \geq 2} (App + NC)^{e_2 < 2})$	A, {G, D}, {G1, G3, D1, D3}
9	Stringent	App	$App^{e_1 \geq 2} App^{e_1 < 2}$	$App^{e_1 \geq 2} (App^{e_2 \geq 3} App^{e_2 < 3}) App^{e_1 < 2} (App^{e_2 \geq 3} App^{e_2 < 3})$	B, {M, E}, {M1, M2, E1, E2}
10				$App^{e_1 \geq 2} (App^{e_2 \geq 3} (App + NC)^{e_2 < 3})$ $App^{e_1 = 0} (App^{e_2 \geq 3} App^{e_2 < 3})$	B, {M, E}, {M1, M3, E1, E2}
11				$App^{e_1 \geq 2} (App^{e_2 \geq 3} App^{e_2 < 3})$ $App^{e_1 < 2} (App^{e_2 \geq 3} (App + NC)^{e_2 < 3})$	B, {M, E}, {M1, M2, E1, E3}
12				$App^{e_1 \geq 2} (App^{e_2 \geq 3} (App + NC)^{e_2 < 3})$ $App^{e_1 < 2} (App^{e_2 \geq 3} (App + NC)^{e_2 < 3})$	B, {M, E}, {M1, M3, E1, E3}
13			$App^{e_1 \geq 2} (App + NC)^{e_1 < 2}$	$App^{e_1 \geq 2} (App^{e_2 \geq 3} App^{e_2 < 3})$ $(App + NC)^{e_1 < 2} (App^{e_2 \geq 3} App^{e_2 < 3})$	B, {M, F}, {M1, M2, F1, F2}
14				$App^{e_1 \geq 2} (App^{e_2 \geq 3} (App + NC)^{e_2 < 3})$ $(App + NC)^{e_1 < 2} (App^{e_2 \geq 3} App^{e_2 < 3})$	B, {M, F}, {M1, M3, F1, F2}
15				$App^{e_1 \geq 2} (App^{e_2 \geq 3} App^{e_2 < 3})$ $(App + NC)^{e_1 < 2} (App^{e_2 \geq 3} (App + NC)^{e_2 < 3})$	B, {M, F}, {M1, M2, F1, F3}
16				$App^{e_1 \geq 2} (App^{e_2 \geq 3} (App + NC)^{e_2 < 3})$ $(App + NC)^{e_1 < 2} (App^{e_2 \geq 3} (App + NC)^{e_2 < 3})$	B, {M, F}, {M1, M3, F1, F3}

change intervention design [22,23]. The App centers around a native menu planner targeting carbohydrate periodization behaviors in athletes. A separate paper will describe the development process and the

behavioral change techniques implemented in this App. Fig. 3 shows the key screens from the App.

In the App, the carbohydrate periodized menu planner is a weekly

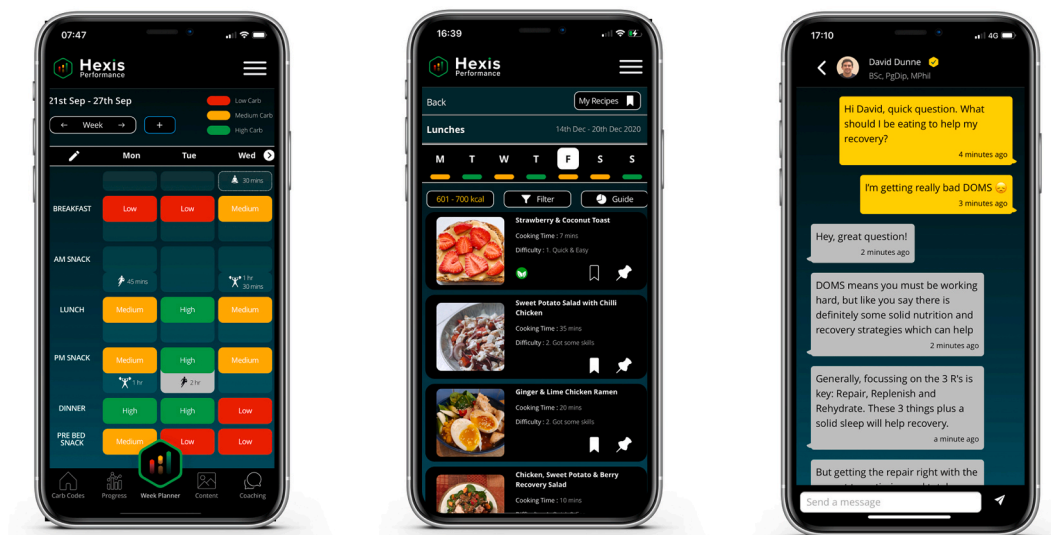


Fig. 3. The carbohydrate periodized menu planner suggested energy intake (kcal) and recipes corresponding to a particular meal in the menu planner, and messaging functions (from left to right) on the mobile application (App).

meal timetable that gives guidance pertaining to the appropriate amount of carbohydrate and energy intake per meal according to their training loads (see the left-most screen in Fig. 3). Each meal in the menu planner is labeled as “low”, “medium” or “high” carbohydrate to help easier visualization and understanding of carbohydrate periodization. The carbohydrate recommendations in the menu planner follow the carbohydrate periodization framework by Impey et al. [3,5]. Participants may also click on the meals to view a list of recipe suggestions with matching carbohydrate and energy intake in kcal (see the center screen in Fig. 3). Participants will use the App to generate their personalized carbohydrate periodized menu planner by inputting their weekly training schedules. They may also edit their plans at any time, and the weekly menu planner will be updated instantaneously. We anticipate the participants to input their training schedules once a week and view their menu planners regularly (e.g., daily). Other features include daily educational and motivational infographics, videos, and text articles to further support the menu planner. See Appendix Fig. A.1 for more details.

For the observational phase, the nutritionists will help participants set up the App via webinars, phone calls, or text messages after the participants received the App, as required within the 6 weeks. Email messages will additionally be sent twice per week to remind participants to use the application.

For the pilot SMART, upon receiving the invitation to download the App, participants will be given one webinar on how to set up and use the App. If they were unable to attend, participants will be sent the webinar video afterward to watch on their own. All participants in the SMART study will additionally receive three reminder push notifications per week via the App.

2.2.2. Nutrition coaching (NC)

Participants who will be randomized to receive nutrition coaching (NC) will have the “Coaching” feature on the App (see the right-most screen in Fig. 3 and Appendix Fig. A.1) activated, and a qualified sports nutritionist will start a conversation with the participants within two days of being assigned nutrition coaching. For the usual nutrition coaching in the observational phase, coaches will send ad-hoc messages and arrange for phone calls, where suitable, with the participants throughout the 6-week study period. The coaches will decide the frequency and type of communication based on their experience. For the pilot SMART, coaches will only communicate with participants during the periods when participants will be given NC as described in Fig. 2. Coaches will be allowed to initiate conversations up to 3 times per week and give ad-hoc calls where suitable according to their expertise judgment only during the eligible periods. Although the coaches may vary the messaging and call frequencies based on their expert judgment, the consensus will be 2–3 times messaging per week and arrange one phone call per participant (where eligible in the pilot SMART phase). In the event the participant is not engaging with the coach, the coach may attempt to call the participant up to two times. Coaches will also be advised to focus solely on nutrition advice.

2.3. Determining design parameters for pilot SMART phase

2.3.1. Tailoring variable: engagement rate

As described in Section 2.1.2, the weekly engagement rates (e_1 and e_2) will be used as the tailoring variable to determine the participants’ response status (i.e., whether they will be re-randomized in Fig. 2). The engagement rate is defined as the number of days at least one App usage log event was recorded in 7 days (i.e., week 1 day 1 to day 7 and week 2 day 1 to day 7). The types of events that constitute an App usage log event are “login”, “logout”, “open”, “close”, “pause”, and “resume”. Engagement is chosen as the tailoring variable as it is relatively objective compared to other self-reported measures, is a type of passive data, and thus requires no additional action from the participants. This mitigates the risk of non-compliance due to missing intermediate data. Given that

participants have little external nutrition support, and the construction of a menu plan that follows carbohydrate periodization requires substantial expertise, we made the reasonable assumption that the engagement on the App is a good proxy to the participants’ adherence to carbohydrate periodization behavior.

Since there is no a priori information on a suitable threshold for the engagement rate, part of the SMART involves exploring different thresholds. Yan et al. [24] has recently shown via simulations that there exists an optimal threshold, which can give the best overall results. It is found that for the healthy population, the engagement with health apps ranges from twice a day to less than once a month, of which about 30% engaged a few times a week or less [25]. Since the App was designed such that the participants make weekly plans, the minimum reasonable engagement rate is thus once a week. Therefore, we proposed the threshold ranges to be from 1 to 3 days/week. We will explore two pairs of thresholds (for two time-points), defining the pairs as relaxed and stringent response criteria (relaxed: $e_1 \geq 1$ day and $e_2 \geq 2$ days; stringent: $e_1 \geq 2$ days and $e_2 \geq 3$ days, where e_1 and e_2 are the engagement rates at end of week 1 and week 2 respectively). Note that by exploring the different thresholds, we are also exploring when (in terms of App engagement performance) the human nutrition coaching should be given.

2.3.2. Randomization time-points

The time-points (end of week 1 and week 2) and the intervals were intentionally made relatively short and close to the baseline for many reasons. Firstly, it is notorious that health apps have low engagement and high dropout rates [25]. A large-scale study on app-usage data reported that on average, at least 65% of the users dropped the app within the first week [26]. Another industry report by Liftoff and AppsFlyer [27] found that the retention rates at day 1, day 7, and day 30 was 20.2%, 8.5% and 4% respectively for health and fitness apps. Secondly, based on experts’ consensus and literature [28], earlier nutrition coaching may potentially be more beneficial for the participants. Thus, any changes to the intervention (App or App + NC) should be given promptly. Following that the participants are expected to plan their meals weekly, we define the randomization time-points to be one week apart.

2.4. Ethical aspects

The study has been registered at [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT04487015) and ethical approval was obtained from Liverpool John Moores University Research Ethics Committee.

2.5. Participants and recruitment

The study will recruit a total of at least 900 participants over 18 years of age for both the observational and pilot SMART phase. Participants must be either elite or amateur athletes taking part in regular training (three or more sessions a week). They must own a smartphone and be willing to provide informed consent. Participants will not be eligible if they report having or previously have had an eating disorder or suffered from disordered eating. Participants will be recruited through direct contacts with gatekeepers, nutritionists, or owners of various sports and training organizations in the UK.

For the observational phase, we expect to recruit $n = 500$ participants with little to no existing nutrition coaching support to use the mobile application and $n = 250$ participants with regular existing nutrition coaching support. The existing coaching support status is determined by whether the participants’ organizations have access to a nutritionist at least one day a week at their sporting organization. For the pilot SMART, we aim to recruit $n = 150$ participants. The numbers were estimated from practical recruitment potential. We aim to recruit as many as possible primarily because of challenges in (1) non-compliance and attrition in longitudinal eHealth studies and (2)

novelty of the approach in sports nutrition and athletes. We will aim to maximize retention while gathering as much information as possible. The sample size for SMART was also referenced from calculating the precision-based sample size [24] and through simulations of the number of resulting participants in each subgroup. As viewed in Fig. 2, there are 18 different possible design pathways for an individual and hence 18 subgroups. Assuming equal response rates at the end of weeks 1 and 2, the sample size required for a binary outcome with 18% precision is 134. The same sample size guarantees an average of 99.3% probability of having at least 2 participants in the smallest subgroups [29]. The sample size required drops to 75 if it is sufficient to assume an 82.4% average probability. All simulations and sample size calculations were done using R 3.6.1 [30]. A table of sample sizes and probabilities may be found in Appendix Table A.2.

2.6. Randomization procedure

In the observational phase, access to the App is predetermined by existing organizational nutrition support for each participant. In the pilot SMART phase, randomization will occur in a 1:1 ratio using block randomization with the size of 4 at all time points (baseline, end of weeks 1 and 2). The randomization algorithm will be generated using R 3.6.1 [30]. The randomized allocation at baseline, to either stringent or relaxed response criteria, will be based on the return order of the baseline survey. Participants with engagement rates (e_1 and e_2) not meeting their respective response criteria (i.e., the non-responders) will then be re-randomized to either App or App + NC. The allocation orders for the two time points will be based on the timestamp order of account creation on the app. All participants eligible for NC will be assigned to one of the six recruited qualified nutritionists by simple randomization, subject to availability and any conflict of interest pre-declared by the coaches. All assignments will be independent of the nutritionists. Given the nature of the intervention, coaches and participants cannot be masked.

2.7. Data collection and outcome measures

Data will be primarily collected from online surveys, mobile applications, and documentation from nutritionists.

2.7.1. Participant characteristics

Participant characteristics such as age, gender, education level, organization will be collected via baseline surveys. Participants will also self-report the number of nutrition apps currently using or used before.

The personality traits of the participants will be measured using the 30-item BFI-2S questionnaire [31] in the baseline survey. The questionnaire starts with "I am someone who ..." and participants use a 5-point Likert scale (1 = strongly disagree; 5 = strongly agree) to rate each item. The OCEAN (openness, conscientiousness, extraversion, agreeableness, neuroticism) personality traits score may then be calculated.

The need for autonomy and control will be measured by an adapted version of the health causality orientation scale (HCOS) by Smit and Bol [32]. Five nutrition-related scenarios will be presented to the participants (e.g., "You are considering making changes to your diet. How likely are you to ...?"). In each scenario, participants rate two action descriptors, representing an autonomy orientation (e.g., "Decide for yourself which type of changes you would like to make.") and a control (nutritionist) orientation (e.g. "Find a nutritionist who will tell you what to do."), on a 7-point Likert scale (1: strongly disagree; 7 = strongly agree). The adapted version changed phrases to be specific for nutrition and removed the control (peers) orientation that is applicable in nutrition.

The eHealth literacy will also be measured at baseline, by an adapted version of the 8-item eHealth literacy scale (eHEALS) [33]. The statements are modified to specifically refer to nutrition such as "I know how

to use the Internet to answer my nutrition questions."

2.7.2. Primary outcomes

The primary outcomes are the mobile application and coach uptake rates, retention and engagement rates, and success in attaining carbohydrate periodization behavior.

The uptake of the mobile application is assessed by whether the participants' created an account in the mobile application. Nutrition coaching uptake is assessed by whether the participants had replied to the coaches' messages in the App or had a nutrition coaching call with coaches during the study periods.

The retention rate on the app is assessed by the number of days until the participant dropped the app (i.e., day starting from account creation to the day of last usage log event detected). The follow-up period will be at week 7 and week 5 for the observational phase and pilot SMART phase, respectively. The overall app engagement is assessed by the number of days at least one usage log event was detected during the study periods.

Carbohydrate periodization behavior is assessed at baseline and follow-up at week 7 for the observational phase and week 5 for pilot SMART via a 3-day self-reported dietary periodization questionnaire (see Fig. 4). The periodization questionnaire was adapted from the previous work of Heikura et al. [9]. The questionnaire was modified to remove all questions not deemed relevant to the current study following an expert consensus. In the periodization questionnaire, six questions around carbohydrate intake are presented sequentially, participants may skip questions depending on their response to the previous question. The first four questions are multiple-choice questions (see Fig. 4) on whether participants deliberately vary their amount of food/calories intake. The subsequent two questions are on the type of food varied and when they are varied. Depending on their responses, participants can be ranked as "1-not periodizing at all", "2-periodizing energy/kcal only", "3-periodizing both energy/kcal and carbohydrates". Only a score of "3" is considered a successful carbohydrate periodization behavior. The amended questionnaire was trialed with eight athletes (independent of the study participants) who also completed a self-reported three-day food and training diary. Six independent sports nutritionists each assigned a carbohydrate periodization status to each athlete based on their food and training diary data and these results were compared to the questionnaire results to evaluate its reliability. Following this trial, the expert panel made minor amendments to the questionnaire before its use in this study.

The study is considered feasible if 70% of the participants created an account in the mobile application, 20% of these participants continue to use the application after 7 days and observe that more participants with the mobile application intervention achieve successful carbohydrate periodization behavior than those in the control group. It should be noted in the literature [26,27,34,35], retention patterns are generally complex, and retention rates vary greatly (e.g., from an industry average of 11%–65% for the topmost popular applications).

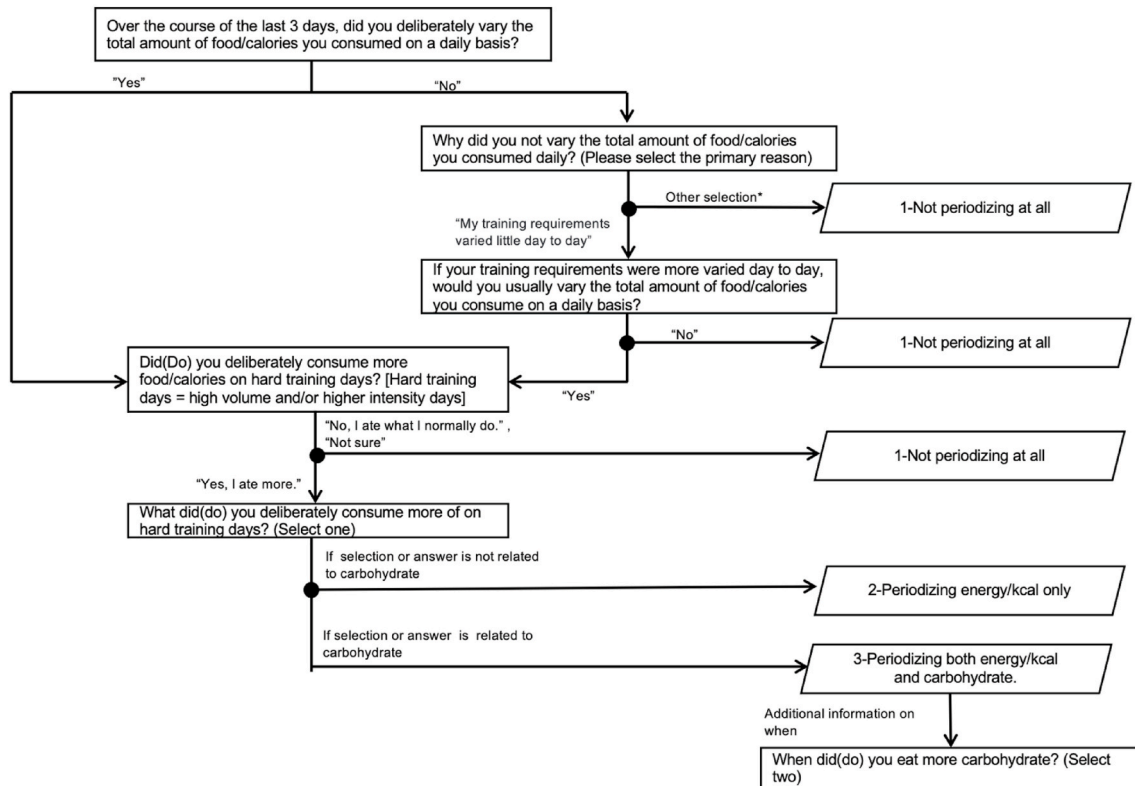
2.7.3. Secondary outcomes

The self-reported weight, goal, carbohydrate periodization self-efficacy, and belief about consequences will also be collected at baseline and follow-up via surveys.

Carbohydrate periodization self-efficacy will be assessed using a 3-item measure adapted from the Self-efficacy for Eating Behaviors Scale [36] and Dieting Self-Efficacy Scale (DIET-SE) [37]. The framework follows the DIET-SE, where statements starting with "How confident are you to ..." are presented, each representing a general scenario-based factor [37], relapse resistant factor [36], and a planning behavior factor [36]. Participants rate each statement on a 5-point Likert scale (1 = not confident at all; 5 = very confident).

The beliefs about consequences of carbohydrate periodization will be measured on a 3-item scale adapted from Thrasher et al.'s [38] research on response efficacy beliefs. Statements aim to capture the participants'

Carbohydrate periodization behavior classification



* Other answers include "My hunger levels were the same every day", "I do not like variation", "I'm not sure".

Fig. 4. The carbohydrate periodization behavior classification is based on responses to questions in the periodization questionnaire at baseline and follow-up surveys.

beliefs about their perceived impact of dietary periodization behaviors on health and performance consequences. All statements start with "How much do you think that adjusting the amount of energy (calories) and carbohydrate you eat, according to your weekly training & competition demands, will benefit your ... ", before continuing to describe three areas: body composition, health, and performance. Participants will rate each statement on a 5-point Likert scale (1 = not at all; 5 = extremely).

2.7.4. Data generated during the intervention

Mobile application (App) generated data, including usage log events (as described in Section 2.3.1), messages, log of recorded weights, and menu planners created, will be recorded. All messages will be encrypted. Phone call and voice message events will also be documented by the nutritionists.

2.8. Statistical analysis

All statistical analyses will be performed using R 3.6.1 statistical software [30]. For both the observational and the pilot SMART phase, descriptive statistics will be used to describe the participants' demographic characteristics, baseline primary and secondary outcome measures (mean and standard deviations for continuous variables, and frequency and percentages for categorical variables). As attrition and non-compliance are expected to be prominent, analyses will be presented using both the intention-to-treat and per-protocol approach, where applicable.

2.8.1. Observational phase analysis

To address the feasibility objective in this phase, we will highlight

the barriers and challenges in delivering a mobile application intervention in the sports nutrition field, including presenting the uptake rates of the application and nutritionists, engagement and usage level of the application, and potential differences in app interactions among different participant characteristics. The improvement from baseline to follow-up and comparison between mobile application and control groups for self-reported behavioral outcome measures will be compared using Chi-square tests for binary outcomes, pairwise t-tests for combined scale scores, and Mann-Whitney U tests for individual items in the scales. Logistic regressions adjusting for baseline characteristics will also be presented. Logistic and linear regressions will also be used to adjust for baseline characteristics.

2.8.2. Pilot SMART phase analysis

The constructed strategies in this three-stage SMART describe the different scenarios under which the App or App + NC may be given at each time-point, given the responses to initial and subsequent interventions under different response criteria (i.e., Table 1) in 4 weeks. We will first address the suitability of the relaxed and stringent response criteria by reporting the response rates at each time point, and the resulting number of participants in the 16 embedded strategies and 18 pathways taken. Depending on the resulting sizes in each pathway, strategy components after the second time point (end of week 2) may not be sufficient for hypothesis testing. Hence, the weighted means of the self-reported behavioral outcome measures for each strategy will primarily be compared empirically. We will also examine the uptake rates of the NC and the change in engagement level when NC is given. We will also consider the design as a two-stage SMART by disregarding the intervention given after week 2, thereby collapsing the 16 strategies into four general strategies (one: 1–4, two: 5–8, three: 9–12, four: 13–16 in

Table 1). The weighted means for the four general strategies will then be compared. Further analyses using logistic and ordinal Q-learning models [29] to identify the optimal decisions (whether to give NC) at each stage will also be considered.

2.9. Novel aspects of the design

The benefits of carbohydrate periodization are well established in sports nutrition. However, adherence and adept knowledge to use the framework poses practical challenges for both athletes and practitioners. There is limited research in sports nutrition on how a digital environment could help improve carbohydrate periodization behaviors in athletes. Hence, the intervention is novel in being the first mobile application to provide a personalized menu planner to athletes that specifically target improvements in carbohydrate periodization dietary behaviors. The three-stage pilot SMART although not novel in concept, is uncommon in practice. It is however fitting in a digital environment where decisions must be made at a higher frequency to reduce participant disengagement.

3. Results

The study started on September 14, 2020 and was completed on January 4, 2021. We are currently in the process of consolidating and cleaning the data.

4. Discussion

The findings of this study will contribute to evidence regarding the use of mobile applications to influence athletes' dietary behaviors in the field of sports nutrition. Specifically, this research will provide insight into the use of a menu planner mobile application and its impact on dietary periodization behaviors in athletes. It will facilitate a greater understanding of how technology may be used to support sports nutrition service provision at scale, while at the same time providing a personalized and continuous experience for athletes.

Additionally, the outcomes of the pilot SMART may be used to inform practitioners on how best to structure the frequency and timing of their communication with athletes when using mobile application supportive solutions to their practice. These findings may help optimize the allocation of practitioner time as well as highlight scenarios where the use of a mobile application alone may be sufficient to help athletes self-manage their dietary periodization behaviors. This may help improve the allocation of resources and potentially also the cost-effectiveness of suggested solutions in practice.

Data generated from the exploratory aims of this research will provide insights into the psychological profiles of elite athletes and the potential impacts, if any, on mobile app uptake and usage. These autonomy and personality-related findings may provide sports nutrition practitioners with useful insights into how best to collaborate with athletes as part of their service provision. Conversely, the barriers and challenges to mobile app uptake and usage identified in this research may provide learnings and guidelines for future similar studies in sports nutrition.

It is worth noting that there are multiple limitations to the current study to highlight. Firstly, the App usage log events may not be the best measure for app engagement (used to construct the tailoring variable in the pilot SMART). In an ideal scenario, a better gauge of an effective App engagement would be to look at their daily App usage duration (by using the usage log events to calculate e.g., time from open to close), and the user journeys on the App (clicks, time spent on each screen, etc). However, this approach poses technical challenges to the current App. There is currently no tracking functionality within the App to capture these user journeys; it is a common issue (verified by initial testing of the app) that log events may be missing at random or systematically, and there may be random time lags between the actual and recorded events.

On the other hand, given how the App works (as described in Section 2.2.1), defining engagement as having at least one usage log event for the day may be sufficient (e.g., viewing the recommended carbohydrate levels for the day, see left-most of Fig. 3). Undeniably, there are non-engagement-related events that are the result of participants directly swiping the App away or accidentally clicking on the App. However, such cases are difficult to identify, unless complete and precise events data are collected.

Secondly, given that the carbohydrate periodization questionnaire is an adaptation of the dietary periodization questionnaire by Heikura et al. [9], it could benefit from more thorough validation.

The questionnaire could have benefited from trialing on a larger group of athletes (currently tested on 8 athletes only) comparing their three-day food and training diaries to the questionnaire results.

Thirdly, there is a high level of uncertainty as to the attrition and non-compliance rates of participants, hence sample sizes cannot be guaranteed. Finally, the mobile application may contain major bugs that could affect usability or participant interest in the application thus diluting its actual effect. Usage of the application may also be influenced by an athlete's competition seasonality, e.g., in-season vs off-season.

Despite these limitations, the current study will provide sufficient foundational evidence on delivering mobile application dietary behavior interventions to athletes and selecting plausible nutrition coaching strategies around the mobile application. Ongoing development of the mobile application will also help overcome potential issues on usability and functionality of the platform, thus potentially improving its overall effectiveness in targeting changing dietary behavior and other relevant outcomes.

Funding support

This work was supported by Applied Behaviour Systems Ltd. Ms. Yan is also funded by Duke-NUS Medical School as part of her Ph.D. Dr. Chakraborty would like to acknowledge support by Khoo Bridge Funding Award from the Duke-NUS Medical School (grant number: Duke-NUS-KBrFA/2021/0040).

Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: The app was developed by Applied Behavior Systems Ltd. Ms Yan, Mr Dunne, Dr Impey, Dr Lefevre, Dr Mazorra are co-founders of the company. Dr Cunniffe is also an advisor of the company. The rest of the authors have no conflicts of interest in the authorship or publication of this study.

Declaration of competing interest

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Acknowledgments

We are grateful to DataSpartan Ltd for providing ongoing technical support for this project.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.cctc.2022.100899>.

org/10.1016/j.conctc.2022.100899.

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