MRC Epidemiology Unit

UNIVERSITY OF CAMBRIDGE

DEBEAT Study

Diet and Eating Behaviours across Early Adulthood Transitions- PILOT STUDY

Protocol
Version 2.0 18/01/2023

1. Background and Rationale

Cardiovascular disease is responsible for 26% of all deaths in the UK[1] and estimated to cost the UK economy £19 billion each year.[1] Poor diet quality is one of the key contributors to poor cardiovascular (CV) health and associated mortality and morbidity.[2] Dietary risk factors are the top contributor to mortality globally,[3] with CV disease the leading cause of diet-related deaths.[4]

Early adulthood is an important period to address development of diet and dietary behaviours. This is the time when prevalence of overweight and obesity rises the fastest,[5] a rise which has accelerated in recent decades.[6] Early adulthood is also a time of rapid personal development, incorporating life transitions such as changes in living arrangements, education/occupational status, relationships and parenthood. These transitions may incorporate changes in social and physical environments and financial resources, identified as determinants of diet and related health behaviours.[7] Time spent in education, different types of employment, or not in education, employment or training (NEET) during early adulthood will also contribute to the development of adult socioeconomic position (SEP), and thus this may represent a key period for the development of social inequalities in diet quality and cardiovascular health.

There has been little study of changes in diet across early adulthood, as demonstrated by my systematic review,[8] and few studies on the association of early adulthood life transitions with changes in diet or lifestyle behaviours.[9–11] In part this is due to the lack of data covering this age range. Analysis of a Norwegian cohort has shown that transitions such as leaving home and leaving education are associated with decreases in diet quality,[12] while analysis of data from the Project EAT study from Minnesota, US finding that fast food intake increases across the transitions of starting work and becoming a parent.[13] Cross-sectional data from the UK population confirms that changes in diet do occur across adolescence and early adulthood in the UK,[14] but further work is needed to understand in detail the relationships between life transitions, eating behaviours and diet during this period.

A wide variety of socio-economic, cultural and environmental determinants have been associated with diet and cardiovascular health. However, there is little known on how changes in these determinants influence changes in diet across the transition from school to further education or employment. Cross-sectional research in the UK has suggested that the social and environmental context of eating influences dietary intake among adolescents, with a higher proportion of discretionary foods consumed out of the home and with friends rather than family.[15] A recent systematic review of factors contributing to diet quality in young adults,[16] has identified a wide range of barriers and enablers of healthy eating, and more recent work with adolescents has aimed to map the perceived drivers of unhealthy diet and obesity.[17] However, there is no high-quality quantitative data currently available in the UK to investigate the determinants of changes in diet

quality across early adulthood. The DEBEAT study will investigate changes in diet from the last year of secondary school, to the following year, investigating how these changes vary between different socioeconomic groups, those following different early adulthood pathways, and the determinants of dietary change in different settings and populations.

The main DEBEAT study will aim to address the following research questions:

1. How does diet quality change from the final year (Y13) of secondary school, to 12 months later?
2. How do changes in diet quality differ between those who transition from secondary school into further/higher education, employment or not in education or employment?
3. How do the changes in the social and physical environment associated with these life transitions influence changes in eating behaviours and diet quality?

In the pilot study, we will test the wave 1 data collection for the DEBEAT study, to test recruitment and data collection methods, and request feedback from participants concerning participation in the study.

2. Objectives

The DEBEAT pilot study aims to achieve the following:

1. Assess the proposed recruitment methods, including school-based recruitment and participant referrals, and gain an insight into percentage uptake per school setting
2. Assess the usability of the email/text invitations for questionnaires and Intake24 invitations
3. Assess completion level of Intake24 and questionnaires, and perceived burden
4. Test questionnaire measures including wording of questions and response options

3. Study design

An observational pilot study taking place in sixth form schools/colleges and further education colleges (referred to as `sixth forms` here on out) in January 2023, aiming for around 100 participants. All students in school year 13 will be invited to take part in the pilot study. Students will be asked to complete a series of web-based questionnaires (outlined in Section 5) across a 14-day period. Reminders will be sent to any participants who haven`t completed any individual questionnaire for up to one month after data collection period (please see figure 1).

4. Recruitment

Sixth forms will be recruited to participate in the pilot study either through the East of England school clinical research network (CRN) or through established contacts in Cambridgeshire schools. A contact teacher will be identified for each sixth form who the study team will liaise directly with. Information about the study will be circulated to all students in year 13 via student email with a link which will take them to the study webpage, Participant Information Sheet (PIS) and link to complete study e-consent. Contact teachers at the participating pilot schools will be asked to encourage students to read the study information in full via the webpage and to sign up to the study if interested.

We will not provide feedback to schools based on pilot data, but schools who take part in the pilot will be encouraged to take part in the full trial in September 2023, where we will provide school-level feedback on diet, health behaviours and wellbeing.

Enrolment

Students will be sent an information email to their school email address which will contain the study recruitment image and provide a brief description of the study and how to get involved. A reminder email will also be sent one week after the original invitation email. Interested students will be directed to click on a link that takes them to the study webpage (https://www.mrc-epid.cam.ac.uk/research/studies/debeat/) where they can read further information about the study, find and read the PIS and the link for consenting to the study. Students will be offered the opportunity to join a zoom information session with the study team prior to consent to ask any questions they may have. They will also be able to send questions directly via email to the study team both prior to consenting and throughout their participation in the study.

Online e-consent will be administered through a purpose built form in Research Electronic Data Capture (RedCap) (outlined further in section 7) which will include obtaining contact information for the students to allow questionnaire links and reminders to be distributed. Screening questions will be asked at the beginning of the e-consent form to identify anyone who may be ineligible to participate in the study. If anyone is deemed ineligible they will not be able to complete the e-consent form. Once consent is received from eligible participants, they will be assigned a study ID which will be unique to them. Participants will be known via this study ID rather than any personal identifiable details (PID) and access to the database linking study ID to PID will be limited to necessary study team members only.

Friend referral

We plan to use the pilot study to test a novel friend referral pathway to aid study recruitment. After a participant provides study consent, they will be provided with a referral code uniquely linked to them that they can provide to their friends to use to sign up to the study. If a referral code is used and results in 3 additional study participants, we will reward the original participant with a £3 Amazon voucher.

Inclusion/Exclusion criteria

Inclusion criteria:
Student in Year 13 at a recruiting school, sixth form or further education college

Exclusion criteria:
Current pregnancy
Diagnosed eating disorder

Incentives

Schools will be offered the opportunity to claim a one off payment of a £200 set up fee which will be provided as a study support cost from the East of England CRN. This will be paid directly to the school from the CRN subject to the school signing a research contract.

Participants will receive Amazon vouchers for completion of measures outlined in section 5. Participants will receive up to £20 in staggered incentives (£3 for each dietary recall, £2 for each questionnaire), and an additional £3 for successfully referring 3 or more friends. These will be sent by the study team to the contact email address provided by the participant following completion of the study.

Feedback

Participants will receive individual feedback on their diet and other health behaviours (e.g. physical activity, alcohol intake), following completion of the data collection. Feedback data will be provided together with comparisons to average data across the study population, to inform how the participant's diet and health behaviours compares with others.

5. Measures

Participants will be asked to complete 4x short questionnaires (15 minutes each) using the REDCap web platform and 3x web-based Intake24 recalls (20 minutes) across a 2 week period, please see figure 1. Participants will be sent an email and text message with a link when each short questionnaire and Intake 24 recall is due to be completed. Completion will be monitored via the study team and reminder notifications will be sent via email and text message to encourage completion. Following completion of the study, participants will be sent a further final questionnaire asking them about their experience of the study completion. Participants will also receive a short 3-question web-based questionnaire six months after study completion which will inform response rates after a period of time since study participation.

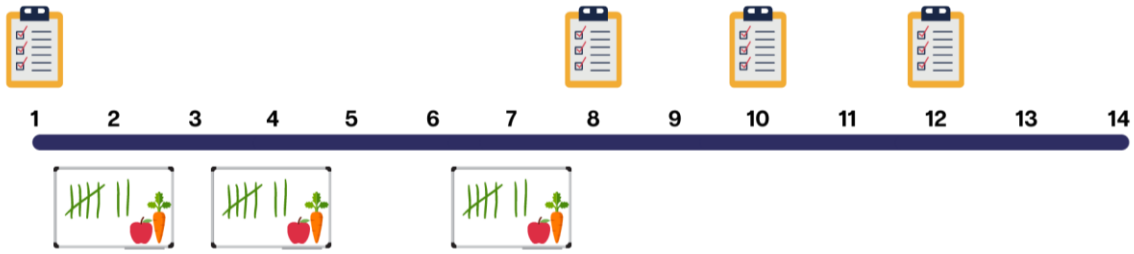

Figure 1: Data collection will be completed over a 2-week period, including 3x Intake24 and 4x 15-minute questionnaires. If data collection is not completed on the requested day, reminders will be sent for up to a maximum of 4 weeks. In addition to this schema, a pilot feedback questionnaire will be issued on study completion and a short questionnaire 6 months after study completion

Questionnaire measures

Participants will be asked to complete the following questionnaires which will be split into 4x 15 minute sessions across the 14 day data collection period. The questionnaires aim to capture individual, social and environmental factors that are likely to influence diet and eating behaviours (see introduction).

Domain	Measures
Baseline demographic data	Race/ethnicity, gender/sex, parental socioeconomic status, family structure, age.
Individual socio-economic position, neighbourhood environment	Current education, employment participation, individual income. Neighbourhood environment: postcode (for mapping to Index of Multiple Deprivation (IMD) scores and neighbourhood food environments)
School/University/Workplace food environment	Education and employment participation Education level and educational establishment attended Job details + industry Work address + postcode (for environment mapping, as above) Availability and accessibility of food within the workplace Work hours and schedule Social support from colleagues for healthy eating Space and facilities for eating Workplace interventions/policies
Home food environment	Living arrangements, household food insecurity, home food availability and accessibility, kitchen facilities, shopping and food preparation, meal structure and setting, social support for healthy eating within the home.
Social environment	Perceptions of support for healthy eating among peers

	Partner relationships, children
Wider health behaviours	Questionnaires on physical activity, sleep, alcohol intake, dieting
Health	Physical health (including self-reported weight and height), mental wellbeing, disabilities.
Pilot feedback	Ease of completion, level of burden, reasons for not completing all measures.

Intake24 dietary recalls

Intake24 is a web-based dietary recall system based on multiple-pass 24-hour recall (https://intake24.org/). On each day that participants complete the Intake24 recall, they will be asked to recall their food and beverage consumption during the previous day. They will also be asked eating context questions, on who the individuals were with, where they were, and where they purchased the food consumed for each meal.

6. Statistics and data analysis

We will aim for 100 pilot study participants, to provide sufficient power to test our pilot study objectives.

Data analysis of pilot data will primarily focus on completion and variability of data collected. Analysis will assess:

- Participation in the study, comparing numbers consenting, and completing the study
- Completion of different elements of the study: questionnaires and Intake24
- Distribution of responses to individual questions
- Responses to pilot feedback questionnaire

7. Data management

Study database

A study database will be created in SQL server by the assigned data manager for the DEBEAT pilot study. It will be stored on the Secure Research Drive (SRD) hosted at University of Cambridge and will only be accessible to core study team members via two factor identification. The database will be used to assign unique study ID numbers to consented participants, store identifiable contact information, create unique URLs for the Intake24 surveys, create reminders for survey completion, record consent information, track friend referral recruitment and send incentives.

RedCap

Participant consent and study questionnaire data will be collected via purpose built forms administered through RedCap; a secure web based application. The e-consent form will be a public link available for completion for all eligible potential participants. The questionnaire links will be participant specific and sent directly to participants via email and text message. Completion of both e-consent and questionnaires will be monitored by the study team through RedCap and relevant reminders sent out for non-completion.

Data Security

The Cambridge Epidemiology & Trials Unit (CETU) within the MRC Epidemiology Unit has an over-arching data management policy (DMP) that encompasses the standards and processes applied to all research and operational activities in the Unit. The Principal Investigator will ensure that all data generated, stored and shared from this trial will be handled in compliance with the DMP and the General Data Protection Regulations. The data controller will be the University of Cambridge. The legal basis for holding and processing the data as outlined in the protocol is to enable the team to conduct health research in the public interest.

Data collected in this research project is electronic using online questionnaires hosted in REDCap. REDCap administrator access is controlled by two-factor authentication and will be limited to necessary study team members and the data manager. Electronic data will be held on the Unit's secure network, collated in version controlled uniquely identified databases. Patients will be assigned a unique participant identifier (PID) which will be unique to them on completion of the e-consent form. All data will be collected and stored using PID and not the participant name. Linkage of PID and patients personal details will be stored in a separate database on the Secure Research Domain (SRD) within the MRC Epidemiology Unit with restricted access to the database manager and the CETU study coordinator. The SRD is an approved safe haven within the University of Cambridge Clinical School which is compliant with the NHS Digital Data Security and Protection Toolkit requirements. The PID will be used for linkage of all study measurements. REDCap and the study database will hold the patients email addresses and phone numbers to send automated emails and text messages to invite patients to complete the online questionnaires and reminders.

Participation will be under full informed consent, including for the storage and use of data collected. At any point, participants can choose to opt out of any aspect of data collection or processing. As stated on the information sheet, any data collected up until the point of withdrawal will continue to be held by the study team.

8. Safety Reporting (AE/SAE definitions)

Adverse Events (AE) or Serious Adverse Events (SAE) will be collected from the start of individual`s participation in the study (defined as providing fully informed consent) until the end of the data collection period.

This is a low risk study with minimal contact with participants and therefore limited opportunity to collect self-reports of AE/SAEs. Therefore, we plan to add in a signposting page at the end of each questionnaire created in RedCap to encourage participants to report an adverse event to the study team, and some related charity helplines e.g. Beat Eating Disorders.

Adverse Events (AE)

If an AE is reported that meets the reporting criteria, an Adverse Event Report Form (CETU_T020) will be completed as fully as possible at the time the event is reported and sent to the study coordinator. The study coordinator is responsible for ensuring appropriate follow up measures have been carried out including contacting participants where relevant and signposting to relevant charity pages/helplines e.g. Beat Eating Disorders.

If an AE doesn't require further follow up, the study coordinator must forward the AE report to the Principal Investigators for review and final sign off.

If an AE does require further follow up, the study coordinator must ensure the appropriate person does this and it is documented on the AE form.

All AEs should be filed in the study's TMF and added to the study`s central log of adverse events.

Serious Adverse Events (SAE)

If an SAE occurs, a Serious Adverse Event Report Form (CETU_T021) will be completed as fully as possible at the time the event is reported and the Study Coordinator will be alerted immediately. The study coordinator should then send the SAE form to the Principal Investigator for an assessment of relatedness and expectedness which will inform further reporting actions. (See CETU SOP015 for further information)

If an SAE is deemed **unrelated** or **expected** by the PIs, it must be documented on the SAE form above but no further reporting is required. The SAE should be filed in the TMF and added to the log of adverse events.

If an SAE is deemed as **related** and **unexpected**, the SAE is subject to expedited reporting and the Sponsor must be notified immediately. The Research Ethics Committee should receive the SAE report within 15 days of the PI's becoming aware of the event. A copy of this form also needs to be sent to the Sponsor. All documentation should be filed in the TMF and added to the log of adverse events.

9. Patient and public involvement

A Young Person's Advisory Group (YPAG) of 15 young people aged 16-20 years have contributed to the design and set-up of the study. Across 5 meetings the YPAG advised on study development, design, data collection methods, participant recruitment and retention and tested the study recruitment materials and data

collection methods. A further 4 meetings are planned, one in the run-up to the pilot study, and 3 following pilot study, to inform further development of the DEBEAT study.

10. Study Advisory Group

The Study Advisory Group provide advice to the investigators on all aspects the design and implementation of the study. The Study Advisory Group is comprised of the following professionals:

Dr Miranda Pallan, University of Birmingham (Chair)

Prof Mireille Toledano, Imperial College London

Dr Laura Johnson, Natcen

Dr Charlotte Cuddihy, Public Health Registrar, East of England

Ian Harvey, Sixth Form school teacher

Dr Esther van Sluijs (MRC Epidemiology Unit)

11. Dissemination

The findings from this pilot study will not be formally disseminated, but will be used to inform our own development of the full DEBEAT study, due to take place from September 2023 – December 2024.

12. References

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