DIPLOMA and Re:Mission. The value of real-world evaluation in improving diabetes care

LOUISA ELLS,[1] PETER BOWER,[2] TAMARA BROWN,[1] RHIANNON HAWKES,[3] SARAH COTTERILL[4]

Br J Diabetes 2024;**24**:ONLINE AHEAD OF PUBLICATION
https://doi.org/10.15277/bjd.2024.430

Key words: diabetes, DIPLOMA, evaluation, Re:Mission

In the last decade NHS England have launched two significant diabetes programmes in response to the concerning increases in the prevalence of type 2 diabetes (T2DM) and the resulting financial and health impact.[1] These services are the NHS Diabetes Prevention Programme (NHS DPP), which was first rolled out in 2016 as a pilot programme,[2] and reached national coverage in 2018;[3] and the NHS Low Calorie Diet programme, which was launched as a pilot programme in September 2020 and was rolled out nationally in June 2023 as the Type 2 Diabetes Path to Remission (T2DPR).[4] Both programmes were based on robust trial evidence: the NHS DPP was informed by diabetes prevention trials worldwide,[5-10] and the T2DPR was informed by the Doctor Referral of Overweight People to Low Energy total diet replacement Treatment (DROPLET)[11] and Diabetes Remission Clinical Trial (DiRECT) trials.[12] These studies were extremely important in establishing the safety and efficacy of these approaches but the evidence was limited concerning participant diversity and the delivery models that needed to be adapted to facilitate real-world delivery at a national scale. Real-world evaluation of these programmes was therefore critical in informing the safe and equitable implementation across our broad and diverse populations, and ensuring effective delivery within the constraints and competing demands of local health systems.

The DIPLOMA and Re:Mission studies were funded by the National Institute for Health and Care Research (NIHR) Health and Social Care Delivery Research, to undertake a real-world mixed-method evaluation of the NHS DPP and T2DPR, respectively.[13,14] The aims and methods of the two studies were broadly similar, which facilitated cross-study comparison and learning. Both sought to deliver a comprehensive, mixed-method evaluation of these interventions, and to understand long-term cost-effectiveness and issues of equity, acceptability and implementation.[13,15] The teams' ability to be responsive and flexible to real-world changes, and to provide critical learning by bringing together quantitative data, models of behaviour change and qualitative insights, supported by extensive public and patient involvement and engagement, were fundamental to these evaluations.[16,17]

Both studies highlighted variation in the use of behavioural theory and behaviour change techniques across the programmes, which resulted in challenges to programme fidelity during real-world implementation.[18-32] The use of similar methods to evaluate fidelity-enabled comparison of findings across studies addressed a major limitation in the fidelity literature to date. This also facilitated shared learning in which the research teams were able to work with NHS England to improve the behaviour change content in future commissioning rounds of both national programmes.[28,33]

The NHS DPP and T2DPR are both delivered by commercial service providers, to reduce the burden on the NHS and add capacity to NHS services.[34] It took time for both research teams to understand the contexts in which these service providers operated, each with their own staff and systems. This analysis identified common practical challenges such as: (1) the time taken to gain data access, and the impact this has on learning and funding timeframes; and (2) the variation in the level of engagement across commercial service providers commissioned to deliver the programme, and the impact this may have on project timelines, staff resource and parity in data collection.

Our collective research suggested practical ways to increase uptake of these programmes in primary care, including clear discussions about their value to patients and referral staff.[35-39] This learning also reflected broader trends in behavioural interventions, where referral, uptake and retention of both programmes varied according to patient socio-demographics.[40-42]

The Re:Mission findings suggest ways for local health services to address the challenge of health inequalities: adoption of an equity perspective at the outset of any new service mobilisation, managing resources equitably from the start and then monitoring ongoing impact on inequality to further target resources.[43] Person-centred care was found to be critically important. This must include referral opportunities and programmes that are culturally competent and tailored to the needs of local populations. Therefore qualitative patient insights will provide important context and understanding, and

[1] The Obesity Institute, Leeds Beckett University*
[2] Centre for Primary Care and Health Services Research, The University of Manchester*
[3] Division of Psychology and Mental Health, The University of Manchester
[4] Faculty of Biology, Medicine and Health, The University of Manchester

** joint lead authorship*

Address for correspondence: Professor Louisa Ells
Professor of Obesity and Co-director of the Obesity Institute, School of Health, Leeds Beckett University, Leeds, LS1 3HE, UK.
E-mail: l.ells@leedsbeckett.ac.uk

will be brought together in six papers to be published simultaneously online in *The British Journal of Diabetes* in April. These papers will showcase the patient insights and learning from the Re:Mission study.

Meeting health challenges in the future is likely to require more large-scale programmes to encourage health behaviour change at scale across our diverse population. The DIPLOMA and Re:Mission evaluations may provide a useful model for evaluation of such programmes.

Conflict of interest Peter Bower has received funding from NIHR for the work reported in this editorial. Tamara Brown has received funding from NIHR and OHID/PHE and has received consulting fees from the British Dietetic Association General Education fund and the European Association for the Study of Obesity in the last three years, and has an academic honorary contract with OHID (2022-2027). Sarah Cotterill has received funding from NIHR for the work reported in this editorial. Louisa Ells has received funding from NIHR, including funding for the work reported in this editorial, MRC, Leeds Council and OHID/PHE in the last three years, and has had an honorary contract with OHID. Rhiannon Hawkes has no conflicts of interest to declare.
Funding Both studies described in this editorial were funded by the NIHR Health Service and Delivery Research Programme (NIHR132075 &NIHR164807). This report presents independent research commissioned by the National Institute for Health and Care Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, MRC, CCF, NETSCC, the HSDR programme or the Department of Health and Social Care.
Acknowledgements We would like to thank Lisa Brunton (University of Manchester), Jamie Ross (Queen Mary University of London), Claudia Soiland-Reyes (University of Manchester), Catherine Homer (Sheffield Hallam University), Kevin Drew (Leeds Beckett University) and Tamla Evans (Leeds Beckett University) for their contribution to content used within this editorial.

References

1. Diabetes UK. How many people in the UK have diabetes? [online]. Diabetes UK 2022, accessed November 2023. Available from: https://www.diabetes.org.uk/professionals/position-statements-reports/statistics
2. Penn L, Rodrigues A, Haste A, *et al.* NHS Diabetes Prevention Programme in England: formative evaluation of the programme in early phase implementation. *BMJ Open* 2018;**8**:e019467. https://doi.org/10.1136/bmjopen-2017-019467
3. NHS England. NHS diabetes prevention programme (NHS DPP) [online]. NHS England 2017, accessed November 2023. Available from: https://www.england.nhs.uk/diabetes/diabetes-prevention/
4. NHS England. NHS Type 2 Diabetes Path to Remission Programme [online]. NHS England 2023, accessed November 2023. Available from: https://www.england.nhs.uk/diabetes/treatment-care/diabetes-remission/
5. Pan XR, Li GW, Hu YH, *et al*. Effects of diet and exercise in preventing NIDDM in people with impaired glucose tolerance. The Da Qing IGT and Diabetes Study. *Diabetes Care* 1997;**20**(4):537-44. https://doi.org/10.2337/diacare.20.4.537
6. Tuomilehto J, Lindström J, Eriksson JG, *et al*. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *N Engl J Med* 2001;**344**(18):1343-50. https://doi.org/10.1056/NEJM200105034418O1
7. Knowler WC, Barrett-Connor E, Fowler SE, *et al.* Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med* 2002;**346**:393-403. https://doi.org/10.1056/NEJMoa012512
8. Kosaka K, Noda M, Kuzuya T. Prevention of type 2 diabetes by lifestyle intervention: a Japanese trial in IGT males. *Diabetes Res Clin Pract* 2005;**67**(2):152-62. https://doi.org/10.1016/j.diabres.2004.06.010
9. Ramachandran A, Snehalatha C, Mary S, *et al*. The Indian Diabetes Prevention Programme shows that lifestyle modification and metformin prevent type 2 diabetes in Asian Indian subjects with impaired glucose tolerance (IDPP-1). *Diabetologia* 2006;**49**:289-97. https://doi.org/10.1007/s00125-005-0097-z
10. Ashra NB, Spong R, Carter P, *et al*. A systematic review and meta-analysis assessing the effectiveness of pragmatic lifestyle interventions for the prevention of type 2 diabetes mellitus in routine practice. London, Public Health England, 2015. Available:https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/733053/PHE_Evidence_Review_of_diabetes_prevention_programmes-_FINAL.pdf [Accessed November 2023].
11. Astbury NM, Aveyard P, Nickless A, *et al*. Doctor Referral of Overweight People to Low Energy total diet replacement Treatment (DROPLET): pragmatic randomised controlled trial. *BMJ* 2018;**362**:k3760. https://doi.org/10.1136/bmj.k3760
12. Lean ME, Leslie WS, Barnes AC, *et al*. Durability of a primary care-led weight-management intervention for remission of type 2 diabetes: 2-year results of the DiRECT open-label, cluster-randomised trial. *Lancet Diabetes Endocrinol* 2019;**7**(5):344-55. https://doi.org/10.1016/S2213-8587(19)30068-3
13. Sutton M. Evaluating the NHS Diabetes Prevention Programme (NHS DPP): the DIPLOMA research programme (Diabetes Prevention Long term Multimethod Assessment). Health Services and Delivery Research programme, project. 2017; https://www.journalslibrary.nihr.ac.uk/programmes/hsdr/164807/ [accessed November 2023].
14. Re:Mission. An evaluation of the NHS Low Calorie Diet Programme [online]. Re:Mission study team 2023, accessed November 2023. Available from: www.remission.study
15. Ells L, Radley D, Homer C. A coproduced mixed method evaluation of the NHS England Low-Calorie Diet implementation pilot. Protocol. Dec 2022. [Accessed November 2023]. Available from: https://fundingawards.nihr.ac.uk/award/NIHR132075
16. Clare K, Ojo A, Teke J, *et al*. 'Valued and listened to': the collective experience of patient and public involvement in a national evaluation. *Perspectives in Public Health* 2022;**142**(4):199-201. https://doi.org/ 10.1177/17579139221103184
17. Hawkes RE, Sanders C, Soiland-Reyes C, *et al*. Reflections of patient and public involvement from a commissioned research project evaluating a nationally implemented NHS programme focused on diabetes prevention. *Res Involv Engagem* 2023;**9**:42. https://doi.org/10.1186/s40900-023-00447-0
18. Evans T, Hawkes RE, Keyworth C, *et al*. The theoretical underpinnings of the National Health Service Low-Calorie Diet Programme: a documentary review and logic model development. *Br J Diabetes* 2022;**22**(1):20-9. https://doi.org/10.15277/bjd.2022.341
19. Evans TS, Dhir P, Radley D, *et al*. Does the design of the NHS Low-Calorie Diet Programme have fidelity to the programme specification? A documentary review of service parameters and behaviour change content in a type 2 diabetes intervention. *Diabetic Medicine* 2023;**40**(4):e15022. https://doi.org/10.1111/dme.15022.
20. Evans TS, Drew KJ, McKenna J, *et al*. Can the delivery of behavioural support be improved in the NHS England Low-Calorie Diet Programme? An observational study of behaviour change techniques. *Diabetic Medicine* 2023:e15245. https://doi.org/10.1111/dme.15245. Epub ahead of print.
21. Hawkes RE, Miles LM, French DP. The theoretical basis of the nationally implemented type 2 diabetes prevention programme:

how is it expected to produce changes in behaviour? International *Journal of Behavioral Nutrition and Physical Activity* 2021;**18**:64. https://doi.org/10.1186/s12966-021-01134-7
22. Hawkes RE, Cameron E, Bower P, French DP. Does the design of the NHS Diabetes Prevention Programme intervention have fidelity to the programme specification? A document analysis. *Diabetic Medicine* 2020;**37**(8):1357-66. https://doi.org/10.1111/dme.14201
23. Hawkes RE, Cameron E, Miles LM, French DP. The fidelity of training in behaviour change techniques to intervention design in a National Diabetes Prevention Programme. *Int J Behav Med* 2021;**28**:671-82. https://doi.org/10.1007/s12529-021-09961-5
24. Hawkes RE, Cameron E, Cotterill S, *et al*. The NHS Diabetes Prevention Programme: an observational study of service delivery and patient experience. *BMC Health Services Res* 2020;**20**:1098. https://doi.org/10.1186/s12913-020-05951-7
25. French DP, Hawkes RE, Bower P, Cameron E. Is the NHS Diabetes Prevention Programme intervention delivered as planned? An observational study of fidelity of intervention delivery. *Annals of Behavioral Medicine* 2021;**55**(11):1104-15. https://doi.org/10.1093/abm/kaaa108
26. Hawkes RE, Warren L, Cameron E, French DP. An evaluation of goal setting in the NHS England Diabetes Prevention Programme. *Psychol Health* 2021;**37**(2):131-50. https://doi.org/10.1080/08870446.2021.1872790
27. Miles LM, Hawkes RE, French DP. How is the behaviour change technique content of the NHS Diabetes Prevention Programme understood by participants? A qualitative study of fidelity, with a focus on receipt. *Annals of Behavioral Medicine* 2021;**56**(7):749-59. https://doi.org/10.1093/abm/kaab093
28. Hawkes RE, Miles LM, Bower P, *et al*. Assessing and ensuring fidelity of the nationally implemented English NHS Diabetes Prevention Programme: lessons learned for the implementation of large-scale behaviour change programmes. *Health Psychol Behav Med* 2022;**10**(1):498-513. https://doi.org/10.1080/21642850.2022.2077205
29. Hawkes RE, Miles LM, French DP. Fidelity to program specification of the National Health Service Digital Diabetes Prevention Program behaviour change technique content and underpinning theory: document analysis. *J Med Internet Res* 2022;**24**(4):e34253. https://doi.org/10.2196/34253
30. Miles LM, Hawkes RE, French DP. Description of the nationally implemented National Health Service Digital Diabetes Prevention Programme intervention and rationale for its development: mixed methods study. *BMC Health Serv Res* 2023;**23**:373. https://doi.org/10.1186/s12913-023-09210-3
31. Hawkes RE, Miles LM, French DP. What behaviour change technique content is offered to service users of the nationally implemented English NHS Digital Diabetes Prevention Programme: analysis of multiple sources of intervention content. *Prev Med Rep* 2023;**32**:102112. https://doi.org/10.1016/j.pmedr.2023.102112
32. Miles LM, Hawkes RE, French DP. How is the behaviour change content of a nationally implemented Digital Diabetes Prevention Programme understood and used by participants? A qualitative study of fidelity of receipt and enactment. *J Med Internet Res* 2023;**25**:e41214. https://doi.org/10.2196/41214
33. Evans TE, Hawkes RE. Working with stakeholders to translate health psychology research into practice: Reflections from evaluations of two national behaviour change programmes. *Health Psychology Update* 2023;**32**(1):17-26. https://doi.org/10.53841/bpshpn.2023.32.1.17
34. Valabhji J. The journey towards implementation of the NHS Diabetes Prevention Programme: a personal perspective. *Diabetic Medicine* 2023;**40**(11):e15238. https://doi.org/10.1111/dme.15238
35. Howells K, Bower P, Burch P, Cotterill S, Sanders C. On the borderline of diabetes: understanding how individuals resist and reframe diabetes risk. *Health, Risk & Society* 2021;**23**:1-2:34-51. https://doi.org/10.1080/13698575.2021.1897532
36. Reeves D, Woodham AA, French D, *et al*. The influence of demographic, health and psychosocial factors on patient uptake of the English NHS diabetes prevention programme. *BMC Health Serv Res* 2023;**23**:352. https://doi.org/10.1186/s12913-023-09195-z
37. Ross J, Cotterill S, Bower P, Murray E. Influences on patient uptake of and engagement with the National Health Service Digital Diabetes Prevention Programme: Qualitative interview study. *J Med Internet Res* 2023;**25**:e40961. https://www.jmir.org/2023/1/e40961
38. Stokes J, Gellatly J, Bower P, *et al.* Implementing a national diabetes prevention programme in England: lessons learned. *BMC Health Serv Res* 2019;**19**(1):991. https://doi.org/10.1186/s12913-019-4809-3
39. Brunton L, Soiland-Reyes C, Wilson P. A qualitative evaluation of the national rollout of a diabetes prevention programme in England. *BMC Health Serv Res* 2023;**23**(1):1043. https://doi.org/10.1186/s12913-023-10002-y.
40. Howarth E, Bower PJ, Kontopantelis E, *et al*. 'Going the distance' - An independent cohort study of engagement and drop out among the first 100,000 referrals into a large-scale diabetes prevention programme. *BMJ Open Diabetes Res Care* 2020;**8**:e001835. http://dx.doi.org/10.1136/bmjdrc-2020-001835.
41. Parkinson B, McManus E, Sutton M, Meacock R. Does recruiting patients to diabetes prevention programmes via primary care reinforce existing inequalities in care provision between general practices? A retrospective observational study. *BMJ Quality Safety* 2023;**32**:274-285. https://doi.org/10.1136/bmjqs-2022-014983
42. Bakhai C, Barron E, Gorton T, *et al*. Early findings from the NHS Type 2 Diabetes Path to Remission Programme (formerly NHS Low Calorie Diet Programme). Diabetes UK Professional Conference; 26 to 28 April 2023, Exhibition Centre, Liverpool, UK.
43. Drew KJ, Homer C, Radley D, *et al.* Equity and local health systems: a qualitative evaluation of the experiences of local health service leads during the first two years of the NHS Low Calorie Diet programme pilot. *Br J Diabetes* 2023;**23**:77-85. https://doi.org/10.15277/bjd.2023.416