Norfolk Diabetes Prevention Study (NDPS)

www.norfolkdiabetespreventionstudy.nhs.uk

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Norfolk Diabetes
NDPS
Prevention Study

- **£ 3.225 M NIHR research programme grant(s)**

- **Clinical Trials Unit , Norwich**

- **2011 - 2018**

- **8 satellite screening and intervention sites**

- **194 practices in Norfolk, NE Essex , Suffolk**

- **146,000 people contacted in 8 CCGs**

- **Population covered 1,887,900**

- **13,500 registered and 12,600 screened**

- **1,540 randomised into trial(s)**

- **Has integrated well with national programme**

Radically upgrading diabetes prevention in England

Mahiben Maruthappu, Harpreet Sood, Bruce Keogh

- National diabetes prevention programme (DPP) launched in 7 large CCG demonstrator sites in population of 1.8 million….

- The programme will initially target up to 10,000 people at high risk of T2DM diabetes ….

- Test innovative ways of finding those at risk ie using the NHS Health checks …

- Combination of physical activity and diet focused behavioural modification..

- Peer support with telephone and online assistance …..

- National framework contract for a diabetes prevention service …

Timelines for NDPS

- Ethical approval on 13.1.2011 to identify and screen > 10,000 high risk individuals in 8 CCGs and randomise into suite of clinical trials.

- The intervention comprises 6 core seminars (months 1-3) and 15 maintenance after-core facilitated discussions over 46 months with bespoke combined diet and exercise intervention.

- Diabetes Prevention Facilitator (DPF) : new role and training programme

- Diabetes prevention mentor (DPM) : people with Type 2 diabetes acting as a lay trainer with peer support ; new role and training programme

- Group delivery to limit costs

- Linked to national vascular screening programme criteria & pharmacy

- Understudied groups with limited evidence base for prevention

- Type 2 diabetes screen detected trial also key element

Original programme structure

Project 1: Screen 10,000 at high risk from 190 practices (146,000 contacted)

Project 2: 1,095 randomised to 46 month RCT
Three arms in trial
Randomised 3:7:7

Project 3 Diabetes Prevention Mentors as peer advisers

Project 4: 420 screen detected T2DM
Three arms in trial
Randomised 1 :1 :1

Project 5 Health economic assessment 1 - 4

Project 6 HbA1c 42 – 47 and NFG
200 in trial
Randomised 1:1

Glycaemic categories and randomisation into NDPS

Fasting plasma glucose (mmol/l)		HbA1c (mmol/mol)	Category
< 5.6	&	< 42	**Normal fasting glucose**
< 5.6	&	42 – 47	**NDH**
5. 6 – 6.1	&	42 – 47	**NDH /IFG**
6.1 – 6.9	&	< 48	**IFG**
≥ 7.0	or	> 48	**Type 2 diabetes**

What are the transition rates to T2DM ,and trial evidence base for prevention in these groups ?

Quality markers and unique elements in NDPS

- **Exercise data** Substantial accelerometry data as an objective measure of physical activity

- **Strong core behavioural science team** : an in-depth mixed-methods process evaluation to test and refine the process model underpinning the intervention.

- **Process analysis** : data on initial behaviour change, behaviour change maintenance, intervention fidelity in regards to intervention delivery

- **Multiple 'real world' NHS glycaemic pre diabetes categories (not IGT)**

- **Adapted to new public policy and diagnostic categories**

- **Limited impact on general practice**

- **Added value from concurrent randomisation of screen detected Type 2 diabetes.**

- **Group delivery of intervention**

- **Intervention delivered by lay trainers with Type 2 diabetes**

Recruitment of lay peer diabetes prevention mentors (DPM) with existing Type 2 diabetes for Project 3 (2014)

- Potential mentors undergo a training programme of seven seminars each lasting two hours in length within a 2 month period. This is medium-high intensity in terms of hours and topics covered

- 14 cohorts of volunteers having been fully trained to date

- The longest serving DPM has volunteered for 46 months

- 1934 calls have been requested of mentors , with a high stable call connection rate of 78% compared with other peer support programmes obtaining only a 45% successful connection rate .

- Average call length is 17.2 minutes duration, which is in line with what is requested of mentors in relation to call length (15-20 minutes) and is comparable with similar interventions

Recruitment of lay peer diabetes prevention mentors (DPM) with existing Type 2 diabetes for Project 3 (2014)

- A stringent recruitment strategy , interview , CRB check, and references.

- 6,077 potential DPM with known Type 2 diabetes contacted through 35 local GP surgeries, and 397 invited from secondary care.

- 310 (5.1 %) expressed interest in the DPM role

- 290 (93 %) passed the initial recruitment stage

- 78 (25 %) offered the role and began training.

- 28 (35 %) have withdrawn from the DPM role, nearly all due to work commitments a rate of withdrawal much lower than similar peer interventions which report withdrawal rates of 50% .
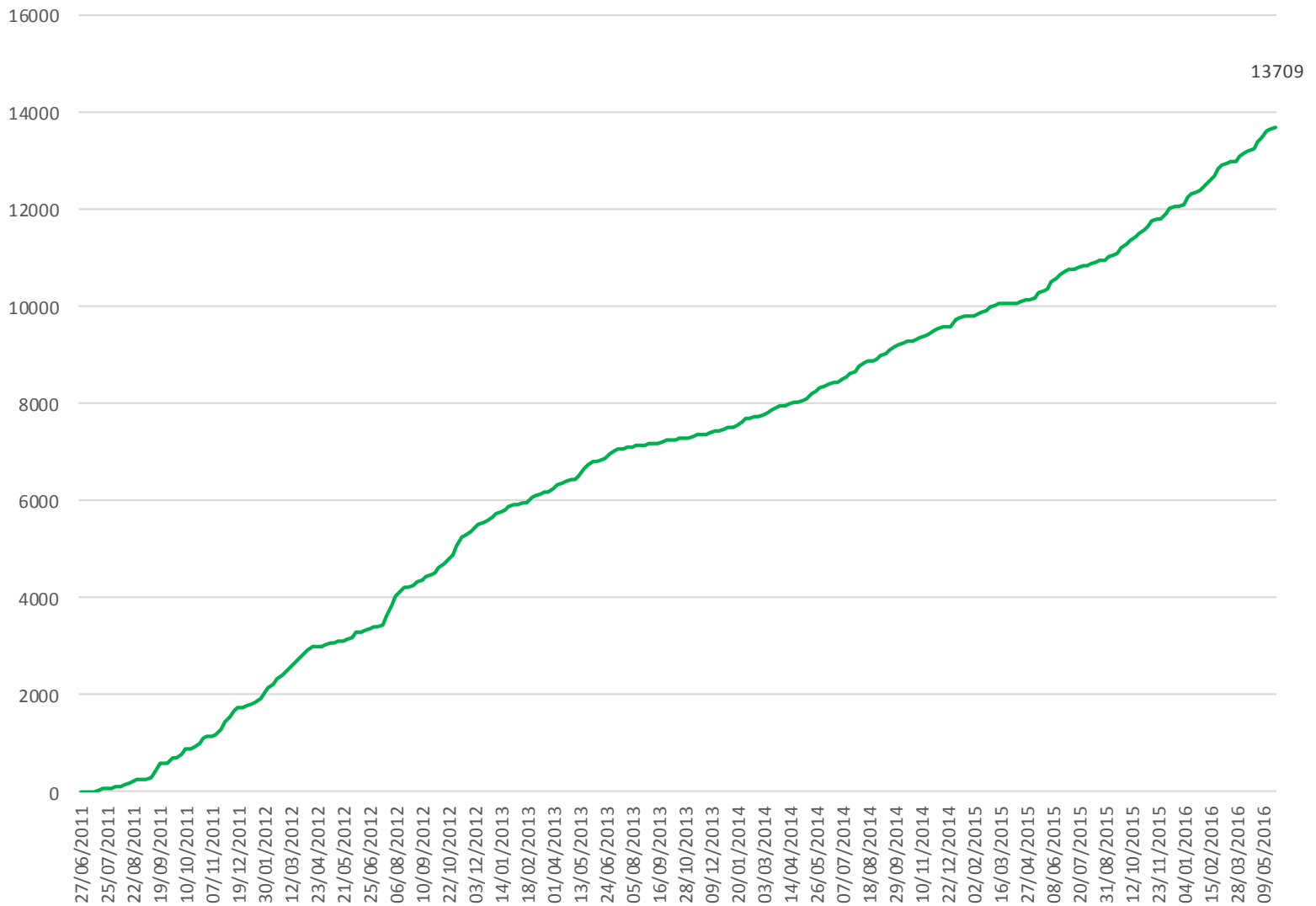
Participant registration (30/05/2016)

Impact on practices and database searches for eligibility

- **Workload 'neutral' for practices but supported through RISP funding**

- **Pre structured database interrogation for Systm1 or EMYS**
  - Age > 40 yrs and BMI > 30 kg/m2 *or*
  - Any previous record of IFG , IGT, non - diabetic hyperglycaemia (category or raw data)
  - Mailshot via Doc Mail and invitation to screening
  - Paired baseline measurements for classification
  - > 140,000 contacted since 2011

- **Prevalence (databases 135 practices)**
  - 10.2% response and attendance rate for screening

  - 11% contacted as age > 40 and BMI > 30
  - 1.7% contacted as IFG
  - 2.7 % as HbA1c 42 – 47 mmol/mol & fpg > 5.6 – < 6.1mmol/l

  - 24.2 % had a randomisable category based on HbA1c and/or glucose based on these simple search criteria in first 10,000 screened

Distribution of glycaemic categories in 10,000 high risk participants screened for randomisation into the Norfolk Diabetes prevention Study (NDPS)

		HbA1c (mmol/mol)		
		< 42	≥ 42 − <47	≥ 48
Fasting plasma glucose (mmol/l)	**< 5.6**	6057 (60.6%)	990 (9.9%)	59 (0.6%)
	≥ 5.6 – 6.0	968 (9.7%)	625 (6.3%)	91 (0.9 %)
	≥ 6.1 – 6.9	306 (3.1%)	487 (4.9%)	174 (1.74%)
	≥ 7.0	11 (0.1%)	70 (0.7%)	162 (1.6%)

Discordance between various non diabetic hyperglycaemia (NDH) subcategories, by HbA1c (and fasting plasma) in 7333 NDPS subjects, with NDH categories based on paired data

Fasting Glucose (mmol/l)	<42						42 - 47					
	<5.6		5.6 – 6.9		≥7.0		<5.6		5.6 – 6.9		≥7.0	
n	4773	(83.1)	960	(16.7)	12	(0.2)	657	(42.4)	827	(53.3)	67	(4.3)
Age, mean (sd)	60.6	(9.9)	62.9	(9.4)	69.9	(9.0)	64.7	(9.7)	64.7	(9.6)	64.4	(9.2)
HbA1c (mmol/mol)	37.1	(2.7)	38.6	(2.2)	38.9	(2.4)	43.2	(1.3)	44.0	(1.5)	44.6	(1.5)
Fasting. Glucose (mmol /l)	4.9	(0.4)	5.9	(0.3)	7.1	(0.2)	5.1	(0.3)	6.1	(0.3)	7.3	(0.3)
BMI (Kg/m2)	30.6	(7.6)	30.4	(5.2)	30.8	(7.0)	32.1	(6.2)	31.2	(5.5)	30.7	(5.4)

Data as n (%)

Norfolk Diabetes Prevention Study (NDPS) and the NHS England programme

- Reports in Summer 2018

- Will answer questions on efficacy of this intervention in understudied categories with limited trial data (NDH /NDH with normal fasting glucose)

- Screen detected T2DM – will intervention have value in T2DM management ?

- Efficacy of peer intervention in T2DM prevention ?

- Most practices in 8 CCGs in East of England already have NDPS derived EMYS or Systm1 database searches stored

- 15.4 % of patients on practice databases eligible for contact

- Screening prevalence of randomisable categories about 25% for NDH or IFG, using simplest possible data searches, with no addition risk modelling or variables that may not be recorded (cf NCVIN modelling)

Norfolk Diabetes Prevention Study (NDPS) and the NHS England programme

- Minimal impact on practices and > 75 % practices engage early

- Intervention fidelity and process analysis for NDPS intervention

- Training manuals and structure for DPF and DPM

- About 10% consent for screening for a high intensity 46 month intervention

- Need to assume about 8,000 T2DM subjects needed to generate 80 trained peer trainers

- Issues about categorisation based on single entry point – very high rates of very short term regression to normal.

- Useful data in modelling for implementation of national programme.

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