The intervention in ADDITION

Description of the centre specific intervention in the intensive arm

June - Sept 2006

Updated Sept 2007 and May 2010

In overall

The aim of the intervention is to optimise the management of blood glucose, blood pressure, blood cholesterol, microalbuminuria and cardiovascular risk among people with screendetected type 2 diabetes recruited to the ADDITION study.

The ADDITION study, will quantify the effect of intensive treatment in people with screen detected diabetes on cardiovascular events and mortality. Patients detected with diabetes by screening receive either routine care (RC) or intensive treatment (IT) according to their practice group randomisation. In the RC group care is delivered by the GP according to national and local recommendations. Intensive treatment follows an overall model with centre specific modifications. The aim of the intensive treatment intervention is to use treatment targets, management algorithms and a range of additional approaches to optimise the management of blood glucose, blood pressure, blood cholesterol, microalbuminuria and cardiovascular risk among the people with screen-detected type 2 diabetes.

A detailed description of the specific activities undertaken to promote intensive treatment in each centre is provided in the subsequent text.

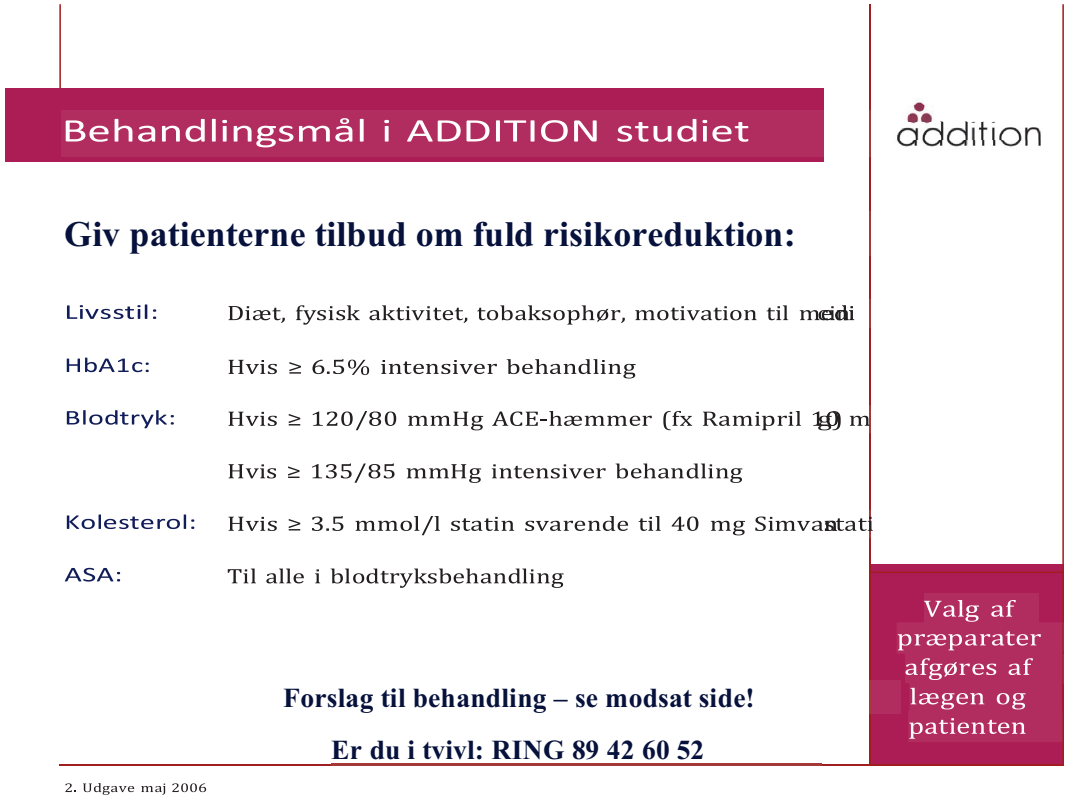
The ADDITION 'intensive treatment' intervention in Denmark.

Practitioner level

Model of care:

- The GPs in the intervention arm is responsible for the care of patients with type 2 diabetes. In some of the included practices the 3-monthly visits are undertaken by nurses. The GPs are nevertheless always responsible for the care. Initiation and all changes of pharmacological treatment are done by the GP. GPs are encouraged to use patient-centred consultations. All GPs are able to refer patients to an outpatient clinic for a second opinion if necessary.

Treatment guidelines:



Behandlingsmål i ADDITION studiet

addition

Giv patienterne tilbud om fuld risikoreduktion:

Livsstil:	Diæt, fysisk aktivitet, tobaksophør, motivation til medi
HbA1c:	Hvis ≥ 6.5% intensiver behandling
Blodtryk:	Hvis ≥ 120/80 mmHg ACE-hæmmer (fx Ramipril 10) m
	Hvis ≥ 135/85 mmHg intensiver behandling
Kolesterol:	Hvis ≥ 3.5 mmol/l statin svarende til 40 mg Simvastati
ASA:	Til alle i blodtryksbehandling

Valg af præparater afgøres af lægen og patienten

Forslag til behandling – se modsat side!

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2. Udgave maj 2006

Educational content:

- Meetings at the end of the normal working day's (2 hours) ○ Every ½ year during the first 2½ years, and thereafter yearly ○ All intervention practice staff are invited (arranged in each county) ○ Topics: treatment targets, treatment strategies, diet, insulin treatment, eye complications, discussion of cases

Educational materials:

- Slides made for the meetings are distributed to all practices together with a summary of the meeting topics.
- Reports describing the status of each of the patients are sent to practices a total of four times during the study period.
- Newsletters are sent to intervention practices, these include a description of study status and new published recommendations about diabetes from the general practice organisations and other scientific associations.

Financial incentives:

- Consultations for screening, and care for diabetes are reimbursed by the NHS as normal consultations. In the first year after diagnosis GPs in the IT group are encouraged to carry out three "long" consultations with the aim of discussing lifestyle changes, disease development and principles of pharmacological treatment. This "long" consultation is supported by funds equivalent to three times a normal consultation fee (approximately 45 Euros). In addition, the

Intervention practices in the intervention arm are reimbursed to report on Case Record Forms (CRFs) at months: 0, 3, 6, 9, 12, 18, years 2, 3, 4, 5 and 6.

Reminders/recall/prompts:

- Twice per year intervention GPs are prompted by mail if CRFs are not returned within three months.

Audit and feedback:

- GPs are sent reports summarising current treatment and levels of blood pressure, HbA_{1c}, cholesterol and BMI, for each of their patients and providing advice concerning how to optimise treatment.

Academic detailing:

- Offices of all participating intervention GPs are visited by the PIs: Torsten Lauritzen or Annelli Sandbaek.
- Subsequently practices whose patients are not meeting the treatment targets are visited or contacted by telephone on further occasions.
- The material for the academic detailing includes patient specific reports describing treatment targets and advice concerning how to optimise treatment.

Opinion leaders:

- The PIs in the study: KB-J, TL and AS act as opinion leaders. Moreover experts in the field of diabetes are invited to attend the meetings to give a second opinion concerning recently published research or to discuss optimal treatment strategies.

Target setting:

- The GPs were informed that in the process of reaching the overall trial targets more steps with individualized target setting for each patient is appropriate.

Patient level

Recommendation for frequency of contacts:

- 3 Monthly
- When a new pharmacological treatment is initiated more frequent contacts are recommended

Educational content and Educational materials::

- All GPs in the intervention arm are provided with a list of topics and educational material suitable for consultations with patients. The topics are:
    - Information about diabetes and its complications ○ Smoking cessation ○ Diet ○ Physical activity ○ Foot care

Reminder/recall/prompts

- Patients are reminded to visit their GP if there is no record of an HbA1c test result in the preceding 6 months or a total cholesterol test result in the preceding 12 months. This procedure is repeated every 3 months from mid 2006. GPs are sent a copy of the patient reminder.

The ADDITION 'intensive treatment' intervention in Leicester

Practitioner level

Model of care (who is seeing patients and where, who is prescribing medication):

The intensive treatment follows an intermediate care model, which involves more frequent contact between patients and healthcare professionals (including a diabetes specialist doctor and diabetes specialist nurse) compared to normal current practice. Our Specialist Care Team (specialist registrar and diabetes specialist nurse) is responsible for the care of the IT patients. Prescribing of pharmacological treatment is undertaken by the specialist doctor.

Treatment guidelines:

The guidelines are shown in the attached document.

Educational content:

The Specialist Care Team which is responsible for the treatment of the IT patients follows the protocol, SOP's and treatment algorithms set out for the study.

Financial incentives:

All ADDITION study practices are reimbursed, quarterly, in arrears for the prescribing costs and the additional costs of care associated with earlier treatment of screen-detected cases. Practices in the RC treatment arm receive a higher level of reimbursement to cover the increased consultation frequency (see attached practice reimbursement document). These payments are funded through Support for Science funding in an agreement with the Department of Health, University Hospitals of Leicester and the Primary Care Research Alliance.

Reminders/recall/prompts:

All IT patients are cared for by our Specialist Care Team which follows study SOP's to prompt them with regards to patient contact.

Audit and feedback:

Patient results (RC and IT) from the one year annual review are sent to all GPs in ADDITION. Our Specialist Care Team updates GPs of the IT patients in writing, following every visit, concerning patient progress and any medication changes.

Academic detailing:

Recent evidence concerning intensive treatment (with associated citations) are presented to practices at the initial recruitment visit in handout form.

Opinion leaders:

Our Specialist Care Team undertakes all practice, home and hospital visits for the IT patients, in consultation with Professor Melanie Davies and Dr Kamlesh Khunti, Principal Investigators for the ADDITION – Leicester study.

Target setting:

IT patient treatment targets for control of blood glucose, blood pressure and blood cholesterol levels are included in the treatment guidelines

Treatment targets

HbA1c < 7%*
Blood pressure ≤ 130/80 mmHg
Cholesterol ≤ 3.5 mmol/l

(* requires action at 6.5%)

Patient level

Recommendation for frequency of contacts:

To retain patients the Specialist Care Team sees them at the most logistically convenient place. This may be at the patients' home, their GP surgery or the local hospital.

After every contact with a patient, the relevant GP is sent a formal follow-up letter to apprise them of their patient's progress, changes to treatment or management and any issues raised during the consultation.

The recommended consultation schedule is given below.

Annual consultation schedule
1 hr Specialist Care Team appointments – diagnosis and 2 months (including retinal screen and complications check)
30 minute Specialist Care Team appointments – 4, 6, 8 and 10 months
15 minute Diabetes specialist nurse appointments – 2 weeks and 4 weeks

1hr annual review (including complications check) with Specialist Care Team –

12 months

Plus any further interim contact required or requested by the patients

Educational content and Educational materials:

All IT patients are provided with a standard Diabetes UK brochure at their initial visit and given the option to be educated on how to do home blood glucose monitoring. The IT group are also invited to attend a DESMOND education session within 2 months of diagnosis. The DESMOND program fulfils the recent DOH/DUK criteria on Education Programs for newly diagnosed diabetic patients and is recommended as 'best practice'. Those who cannot attend these sessions have an individual diabetes education session with a Diabetes Advanced practitioner for approximately 1hr.

Desmond
Diabetes Education and Self Management for Ongoing and Newly Diagnosed

The course has a set number of learning objectives which are designed:

- To provide individuals with information regarding the causes, effects and management of type 2 diabetes.
- To enable newly diagnosed individuals to discuss and explore their experiences and successes of living with diabetes.
- To ensure that those living with type 2 diabetes are aware of their specific health risks for developing the complications of diabetes.
- To provide an expert forum for participants to discuss methods of reducing their identified risk factors.
- To support individuals in developing their own diabetes management plan.

The DESMOND Philosophy is:

- Each individual is responsible for the day to day management of their diabetes.
- People make the best possible decisions for themselves to achieve their best quality of life.
- All the barriers to self management lie in the individual's personal world.
- The consequences of self management decisions impact solely on them, their family and carers
- Acquiring new information is not easy.
- Many factors influence self management and we must create the environment to address these.

Reminder/recall/prompts

No reminders are issued to the RC patients from the study team to see their GP, although all patients (RC and IT) are recalled by letter by the Specialist Care Team for measurement at one of our testing centres around one year after diagnosis for their annual review.

The Specialist Care Team organise appointments in line with the protocol for the IT patients through regular telephone contact

The ADDITION 'intensive treatment' intervention in Cambridge

The aim of the intervention is to optimise the management of blood glucose, blood pressure, blood cholesterol, microalbuminuria and cardiovascular risk among the people with screendetected type 2 diabetes recruited to ADDITION. This is achieved through a combination of regular practice-based educational meetings targeting the general practitioner and nurse incorporating guidelines, academic detailing, opinion leaders, target setting and audit and feedback, alongside theory-based educational materials for patients.

Practitioner level

Model of care (who is seeing patients and where, who is prescribing medication):

- The GP and practice nurse are responsible for care. A small proportion of patients are referred to outpatients, for example for consideration for transfer to treatment with insulin as per routine practice. Prescribing of pharmacological treatment is undertaken by the GP.

Educational content:

- Following recruitment and set-up visits for all participating practices, at least three 11.5 hour lunchtime, practice-based meetings have been undertaken with practices in the intensive treatment arm of the study.
- The initial visit focuses on a presentation of the evidence underpinning intensive treatment and a presentation of the treatment targets, treatment guidelines and patient educational materials
- Subsequent visits at around 8 and 16 months after the practice commences screening reiterate the treatment targets and provide an audit and feedback of the practice performance against the treatment targets, and discussions about the management of individual study participants

Educational materials:

- Slide presentation and associated handouts.
- Treatment guidelines.

Financial incentives:

- All ADDITION study practices receive reimbursement for the costs of screening and the additional costs of care associated with earlier treatment of screen-detected cases. Practices in the intensive treatment arm receive a higher level of reimbursement to cover the increased consultation frequency and increased prescribing costs associated with delivering intensive treatment

Reminders/recall/prompts:

- During individual case discussions GPs and nurses are prompted to recall patients if no blood tests have been undertaken since baseline assessment.
- Patient results from one year measurement are faxed to all GPs in ADDITION.

Audit and feedback:

- Interactive practice-based audit and feedback sessions (median 3, range 1 to 4) are organised around 6 and 14 months after the initial education session and annually thereafter. They consist of an interactive discussion of overall achievement against treatment targets and optimisation of the management of individual patients. Standardised data for each study participant are requested from intensive treatment practices prior to follow up visits. The care of each patient is discussed unless the practice has very high numbers of patients, in which case we select patients to illustrate the main issues for each practice.

Academic detailing:

- Recent evidence concerning intensive treatment (with associated citations) is presented to practices at the initial meeting, in handout and algorithm form in the treatment guidelines and during case discussion at follow up visits.

Opinion leaders:

- All practice-based meetings are undertaken by SG and a local diabetes consultant. Both sit on the local Diabetes Managed Care Network (with responsibility for local delivery of the National Service Framework for diabetes) and have been involved with production of the local diabetes guidelines.

Target setting:

- Patient treatment targets for control of blood glucose, blood pressure and blood cholesterol levels are included in the guidelines, initial practice presentations and audit/feedback sessions (see below).

Treatment targets
HbA_{1c} < 7.0% (requires action at 6.5%)
Blood pressure ≤ 135/85 mmHg
Cholesterol <4.5 mmol/l (IHD +ve)
<5.0mmol/l (IHD -ve)

Provision of glucometers for patients:

Capillary blood glucometers and training in their use are provided to the primary care team. However, the decision to offer a glucometer to an individual patient is left to practitioners.

Patient level

Recommendation for frequency of contacts:

- The recommended schedule for consultations, on which financial remuneration is based, is given below.

Annual consultation schedule

5 x 10 minute GP appointments – diagnosis, 2, 4, 6, 9 months
1 x 30 minute GP annual review – 12 months
7 x 15 minute practice nurse appointments – diagnosis, 2 weeks, 4 weeks, 2, 4, 6, 9 months

Educational content and Educational materials:

- Practice nurses were provided with theory-based education materials to give to patients shortly after diagnosis in order to provide a shared framework for discussion of the causes, consequences and treatment of diabetes (Getting Started with Diabetes). The materials were developed by a multidisciplinary team and drew on Leventhal's selfregulation model applied to chronic disease. They cross-referred to 'Diabetes for Beginners-Type 2' a Diabetes UK publication that was included in the patient information pack. The materials stressed the importance of a healthy lifestyle for the control of diabetes and associated health problems. Specifically, participants with a BMI>28kg/m^2 were encouraged to lose 5-10% of their body weight, to increase their physical activity gradually (recommendations to reach the equivalent of 35 minutes of brisk walking per day for 7 days per week), to avoid excessive alcohol intake, to take their medication regularly, to self-monitor their blood glucose level (if applicable) and to attend annual health checks. Participants who smoked were encouraged to stop.

Reminder/recall/prompts

No reminders are issued from the study team, although all patients are recalled for measurement at one of our testing centres around one year after diagnosis.

The ADDITION 'intensive treatment' intervention in the Netherlands

General Practitioner (GP) level

Model of care (who is seeing the patients and where; who prescribes the medication).

Specially trained diabetes study nurses see the patients at three-monthly intervals. At the fourth appointment (the annual check-up) the patient consults the GP. The diabetes nurses are allowed to change the dosage of the prescribed medicine. Also start of new medication may be suggested by the nurse, but new medication is prescribed by the GP. After the diabetes nurse has seen the patient she discusses with the GP possible changes in medication according to the guideline

ADDITION: intensieve multi-farmacologische therapie

	Basis behandeling	**Aanvullende behandeling**			
	Dosering medicatie ophogen met 2 weken interval. Ga naar de volgende stap in de behandeling bij maximale dagdosis. Zie de patient elke 2 weken tot het doel bereikt is; vaker wanneer insuline gestart wordt.				
	Behandel Drempel:	***Indien boven de behandel drempel voeg voeg toe:***	***Indien nog steeds erboven toe:***	**Indien nog steeds erboven**	
HbA_{1c}	≤ 6.5% dieet	> 6.5% • Metformine of • Meglitinide (bijv repaglinide) of • SU (bijv. gliclazide) *Eerste keuze metformine, tenzij..*	> 6.5% • meglitinide (bijv. repaglinide) of • SU (bijv. gliclazide) of • TZD (bijv. rosiglitazone)	> 6.5% Start insuline therapie met of zonder tabletten	
Bloeddruk	≤ 120/80 mmHg geen	> 120/80 mmHg • ACE-remmer (bijv. ramipril) of indien bijwerking: • A2 (bijv valsartan)	> 135/85 mmHg • Ca-antagonist of • diureticum(lage dosis thiazide)	> 135/85 mmHg • diureticum of • Ca-antagonist	> 135/85 mmHg β-blokker (bijv. metroprolol)

Cholesterol	≤ 3.5 mmol/l dieet	> 3.5 mmol/l statine (bijv. simvastatine 40 mg of ander statine in vergelijkbare dosering)	> 5.0 mmol/l statine tot maximum dosering
Acetylsalicylzuur	80 mg voor alle patiënten die behandeld worden met antihypertensieve medicatie		

Education of the GPs in the intervention group

- At the start of the study all GPs are informed, in small groups of 2-4, about the study aim, the treatment targets and the strategies in the ADDITION study.
- In the first year most of our effort went to educating the diabetes nurses. Dr Paul Janssen, a GP and a researcher in the ADDITION study team, met them twice per year. As a spin-off the GPs were reinforced to adhere to the treatment algorithm since the GPs had regular consultations with the diabetes nurses in their own practices. The latter procedure is continued up till now.
- After 12 months the GPs in the IT group are invited for a meeting (9-12 persons) at which the ADDITION treatment guidelines are reinforced.
- From 2005, a postdoc GP, Mrs Meggy van Kruijsdijk, has been trained to encourage the GPs to follow the ADDITION treatment guidelines during practice visits at least annually. In most cases the diabetes nurse is also present during these meetings, during which all ADDITION patients are discussed in detail, depending upon the degree to which treatment targets are met for each patient.
- During the consultations between GPs and diabetes nurses, and between GPs and GP-trainer, the records of all patients are discussed including difficulties in following the treatment guidelines.

Educational materials

No additional educational materials are used.

Financial incentives

The GPs from the intervention group received 55 Euro/year for 5 years handing over relevant data and for attending training and consultations sessions.

Reminders

The diabetes nurse monitors the completeness of the CRFs.

Audit and feedback

This takes place during the consultation between the GP-trainer and the GPs each year. No benchmark is provided. The biomedical values of the patients are compared with the targets from the common ADDITION treatment guidelines

All the GPs in the IT group are visited at least once a year by a GP-trainer (see above)

The purpose of this visit is:

- To monitor the quality of care
- To emphasise the targets of the intervention
- To maintain the interest of the GPs
- To discuss difficulties related to ADDITION, such as:
- Collaboration between GP and diabetes nurse
- Difficulties in following the treatment guidelines

- How to encourage patients to reach target values • If necessary advice is given to improve the treatment.
- If the targets of HbA_{1c}, blood pressure or cholesterol are not reached advice is given such as: extra measurement (including home measurements in the case of blood pressure); increasing dose of medication, adding another cholesterol lowering drug or no action since maximal blood pressure medication (4 drugs) is already prescribed

Patient level

Frequency of contact:

- After screening patients are seen frequently (1x every 3-4 weeks) until they reach most of the target levels
- After reaching targets patients are seen 3 monthly.

Educational content and educational materials

- The diabetes study nurses and the GP's are trained to educate the patient, and educational materials are made available as hand-outs.
- Education was not 'extra-ordinary'. The difference between the IT group and the RC group was more concerned with the treatment guidelines than the life-style advice.
- The nurses are responsible for most of this education. The topics they discuss with the patients are:
- Information about diabetes and complications
- Diet
- Physical activity
- Smoking cessation
- Foot care

Reminder/recall/prompts

Patients are reminded to visit the GP or the diabetes nurse when no laboratory results are available within the scheduled time, e.g. HbA_{1c} 6 months; cholesterol 12 months,

January 2007 Outline of treatment recommendation in the intensive-therapy arm. The protocol allows for advantage to be taken of new drug development and the final decision will depend on the individual doctor and patient.; PGR, prandial glucose regulator; SU, sulphonylureas; BG, biguanide; TZD, glitazone; TD, thiazide diuretic; LD, loop diuretic; IHD, ishaemic heart disease; fbg, fasting blood glucose.

	Basic treatment			**Supplementary treatment**	
	Increase dose over 2-4 weeks intervals; go to next treatment step when maximum daily dose is reached or if side-effects appear. See patient every 2nd week until target is reached, more frequently with the onset of insulin treatment.				
	Treatment threshold:	***If above add***	***If still above add***	***If still above***	
HbA_{1c}	**≤ 6.5%*:** **diet**	**> 6.5%:** **BG (eg Metformin) or** **PGR (eg Repaglinid)** **or SU (eg Gliclazin) or** **TZD (Glitazone)** **Optional first choice**	**> 6.5%:** **PGR (eg Repaglinid)** **or SU (eg Gliclazin)** **or BG (eg Metformin)** **or TZD (Glitazone)**	**>6.5%:** **Continue oral hypoglycaemic medication, add Insulatard 12IU at bed time, increasing with 4-6IU every week until fbg < 7 mmol/l.** **If more than 40 units then divide dose ~~and quit oral drugs~~.**	
BP	**< 120/80 mmHg:** **none**	**≥ 120/80 mmHg:** **ACE-inhibitor (eg Ramipril) low to maximum dose**	**≥ 135/85 mmHg:** **Ca antag (eg amlodipine) or TD (eg bendroflumethiazide)**	**≥ 135/85 mmHg:** **TD (eg bendroflumethiazide) or LD (furosemide) or Ca antag (eg amlodipine)**	**≥ 135/85 mmHg:** **B-blocker (eg metroprolol)**

Cholesterol	**< 3,5 mmol/l:** **none**	**≥ 3.5 mmol/l:** **lipid lowering treatment (eg simvastatin 40 mg)**	**- IHD: ≥ 5.0 mmol/l: diet + statin dose up to maximum + IHD: ≥ 4.5 mmol/l: diet + statin dose up to maximum**	
Acetylsalicylic acid	**75 - 80 mg to all patients treated with antihypertensive agents.**			

* In order to achieve the overall goal of the ADDITION Study, ie to keep the HbA1c under 7%, alterations or additions to therapy should seriously be considered when the HbA1c is > 6.5%.