



# **A prospective randomised controlled trial on the Efficacy of Self-MONitoring in Type 2 diabetes**

Dr Maurice O'Kane

Altnagelvin Hospital

Western Health and Social Care Trust

On behalf of the ESMON Study Group

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**ESMON**  
EFFICACY OF SELF MONITORING

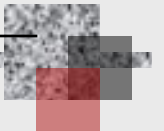


# Aims of ESMON

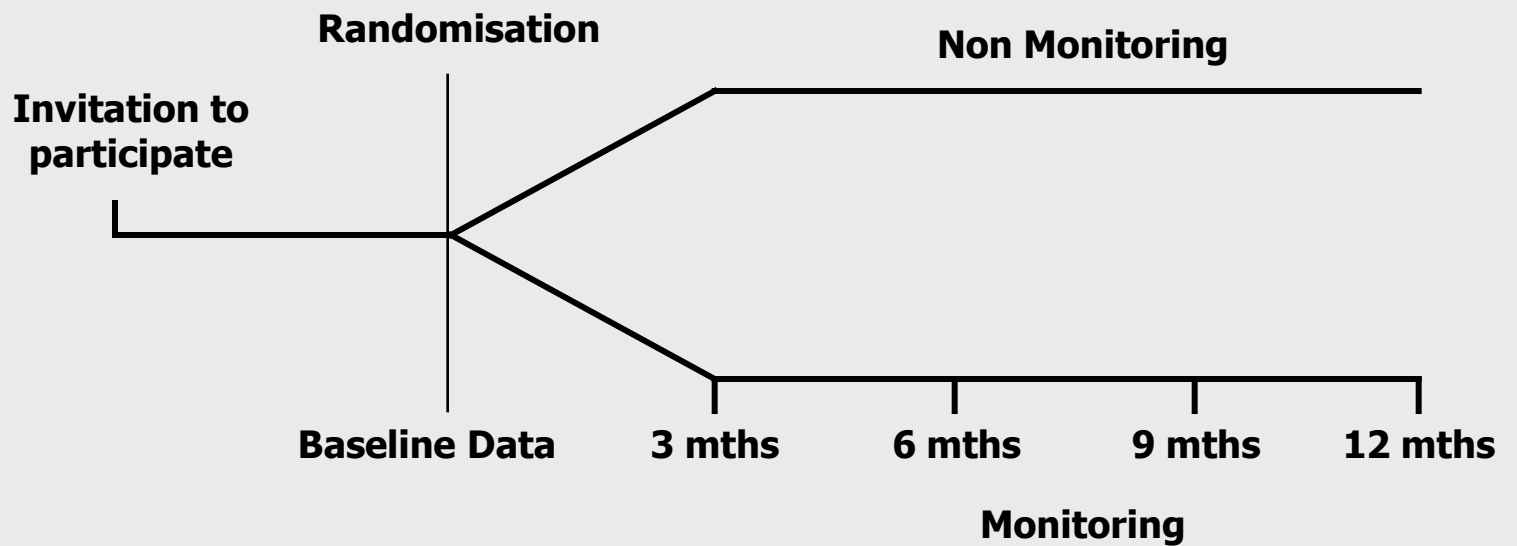
- ◆ To assess the effects of self monitoring on glycaemic control and psychological indices in patients with newly diagnosed T2DM

# Design

- ◆ Prospective randomised controlled trial of monitoring v. non monitoring [control] in patients with newly diagnosed T2DM over a period of 1 year
- ◆ Hospital diabetes clinics

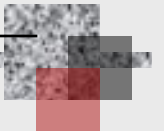


# Study Design



# Exclusion criteria

- ◆ Secondary diabetes
- ◆ Insulin treatment
- ◆ Prior SMBG
- ◆ Major illness within previous 6 months
- ◆ CKD
- ◆ Chronic liver disease
- ◆ Alcohol dependency
- ◆ Oral steroids



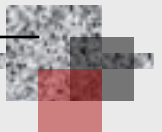
# Monitoring Group

- ◆ Patients asked to monitor 4 fasting and 4 postprandial glucose measurements per week
- ◆ Patients given advice on appropriate responses to high or low readings [diet / exercise only]



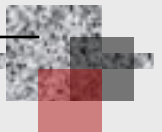
# Protocol for home monitoring

- ◆ Patients asked SMBG 2 / day for 4 days per week (1 fasting & 1 post prandial after main meal)
- ◆ Results to be recorded in diary
- ◆ Training in meter use by DSN – technique observed
- ◆ Advised on interpretation of results: responses to food/exercise/sick day rules
- ◆ Advised to contact DSN if fasting readings 5 out of 7 days  $>10\text{mmol/l}$  or Post prandial  $>12\text{mmol/l}$
- ◆ Asked to confirm symptoms of hypo with a BG result prior to treatment if possible.



# Non monitoring Group

- ◆ Patients were asked not to acquire a meter or perform monitoring for the duration of the study
- ◆ Patients in monitoring and non monitoring group received an identical structured education programme [nurse, dietitian, podiatrist, doctor]



# Treatment algorithm for oral hypoglycaemic agents

HbA1c > 7.5%



Add metformin and titrate to a maximum dose of 2g daily



HbA1c > 7.5% on maximum tolerated dose of metformin



Add gliclazide and titrate to a maximum of 320mg daily



HbA1c > 7.5% on maximum tolerated dose of metformin



Consider addition of glitazone or transfer to insulin as clinically indicated

[SMBG results were available to clinical staff but no algorithm for their incorporation into decisions on pharmacological therapy]

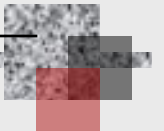
# Study Endpoints

## Primary Endpoints

- ◆ HbA1c
- ◆ Hypoglycaemia incidence
- ◆ Psychological indices

## Secondary Endpoints

- ◆ Differences in weight
- ◆ Differences in OHA regimen



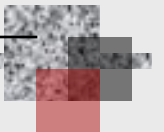
# Psychological Indices

## ◆ Assessed by Questionnaire:

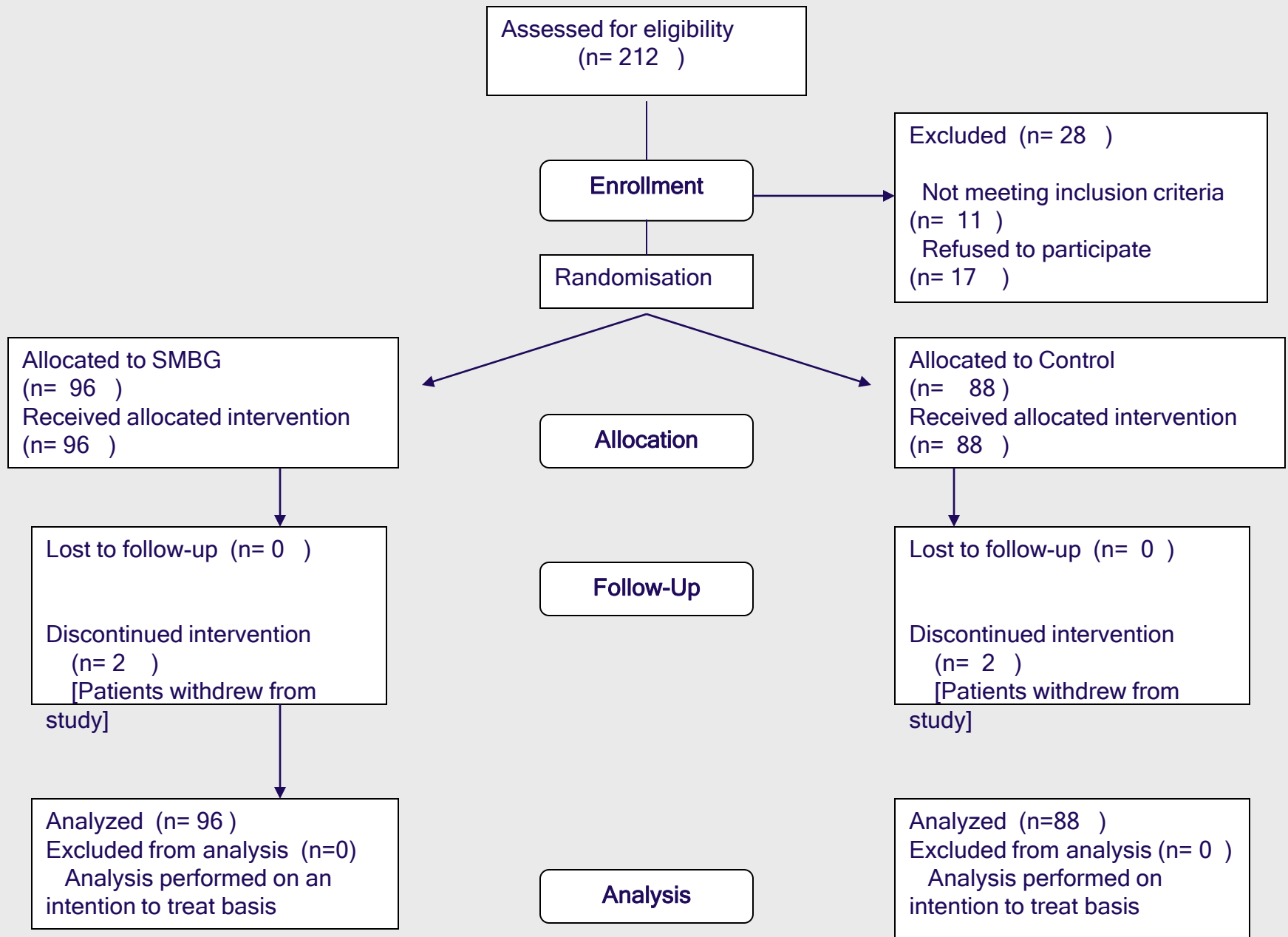
- Diabetes treatment satisfaction [Bradley 1994]
- Diabetes attitude scale [Anderson 1990]
- Well being questionnaire [Bradley 1994]

# Statistical Analysis

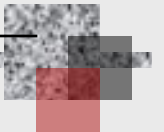
- ◆ Univariate t tests checked against non latent growth models [time invariant / variant covariates: age, gender, monitoring status (compliant/noncompliant); medication]
- ◆ Intention to treat [imputation of missing data by full information maximum likelihood]



# ESMON Study patient flowchart



# Results



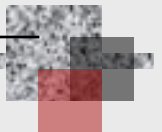
# Baseline characteristics

	Monitoring	Control
Number of patients [male / female]	96 [55 / 41]	88 [56 / 32]
Age Years [SD]	57.7 [11.04]	60.9 [11.5]
BMI kg/m <sup>2</sup> [SD]	34 [6.98]	32 [6.23]
HbA <sub>1c</sub> % [SD]	8.8 [2.1]	8.6 [2.3]

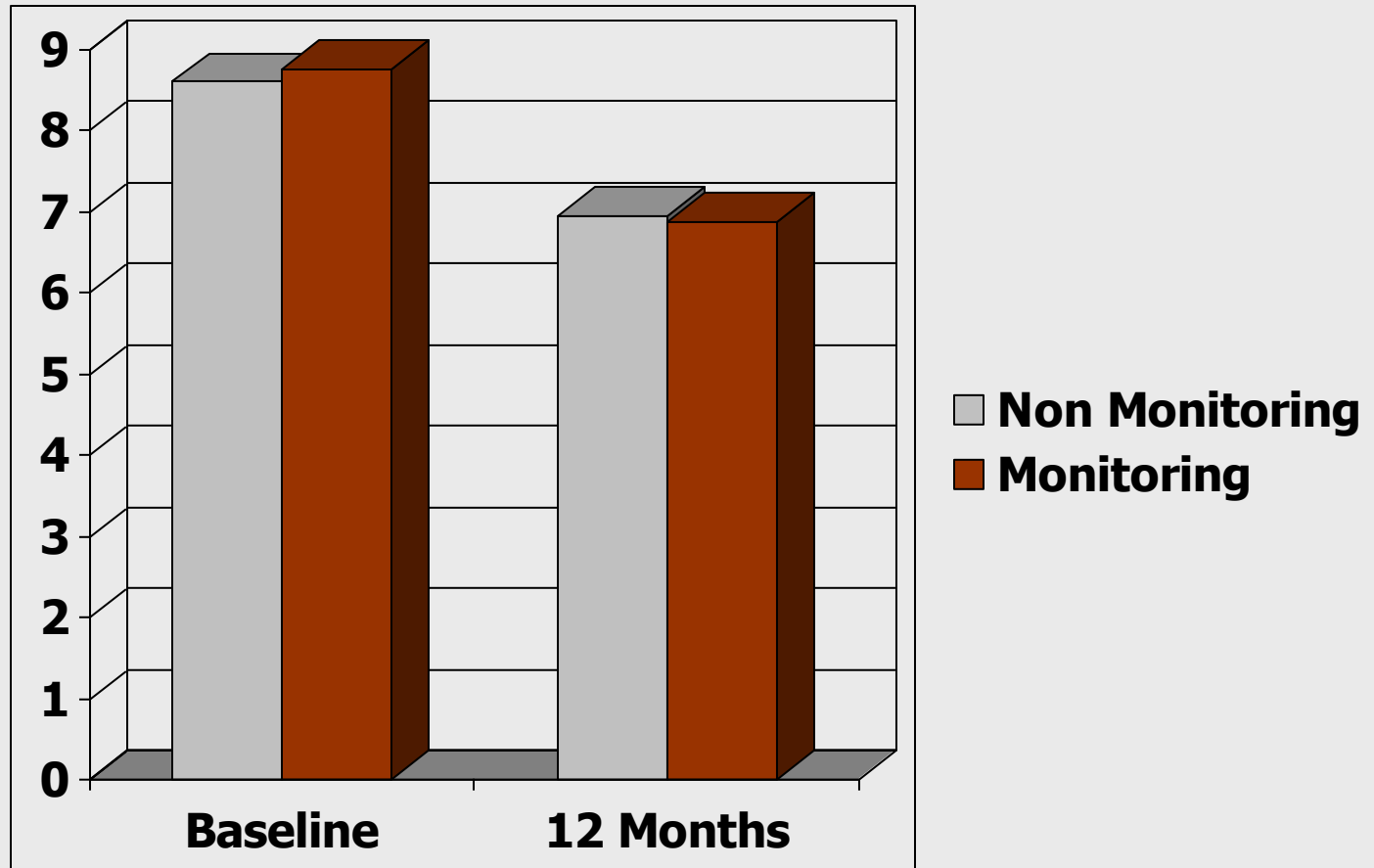


# Concordance with monitoring regimen

- ◆ Concordance with monitoring regimen defined as a monitoring frequency of  $> 80\%$  of that requested
- ◆ Attained by 63 / 96 participants in monitoring limb



# Control Vs Monitoring HbA1c



# ESMON

## HbA1c in monitoring and control groups

Time [Months]	HbA1c Mean [SD]		P value	Mean difference	95% CI for difference
	Monitoring	Control			
0	8.8 [2.1]	8.6 [2.3]	0.68	-0.33	-0.77 to 0.51
3	7.2 [1.1]	7.1 [1.2]	0.50	0.18	-0.47 to 0.23
6	7.0 [0.9]	7.0 [1.1]	0.82	0.04	-0.27 to 0.35
9	6.9 [0.8]	7.1 [1.4]	0.30	0.19	-0.16 to 0.54
12	6.9 [0.8]	6.9 [1.2]	0.69	0.07	-0.25 to 0.38

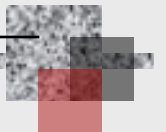
# Self reported hypoglycaemia

	No of patients reporting hypoglycaemia [total no of hypoglycaemia episodes reported]	
Time [Months]	Monitoring	Control
0	1 [3]	0 [0]
3	5 [10]	2 [8]
6	3 [5]	4 [8]
9	5 [9]	1 [6]
12	4 [4]	6 [14]

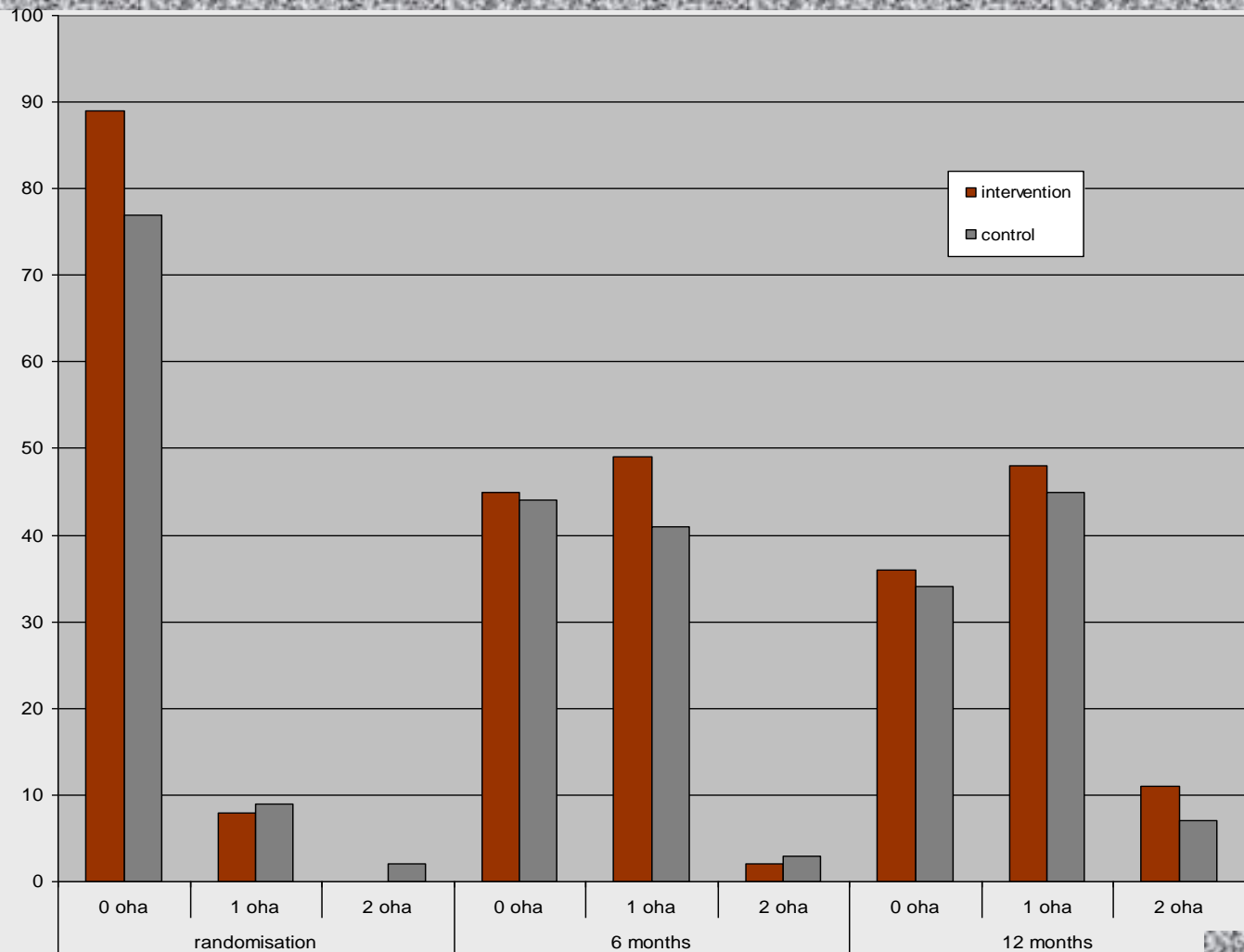
## Analysis of covariance for the effect of monitoring on psychological variables (baseline and endpoint), controlling for a gender

Item	Beta coefficient [Standard error]	p value
Depression	6.05 [2.37]	0.011
Anxiety	5.86 [3.19]	0.07
Positive well-being	4.16 [2.88]	0.15
Energy	- 0.84 [2.83]	0.77

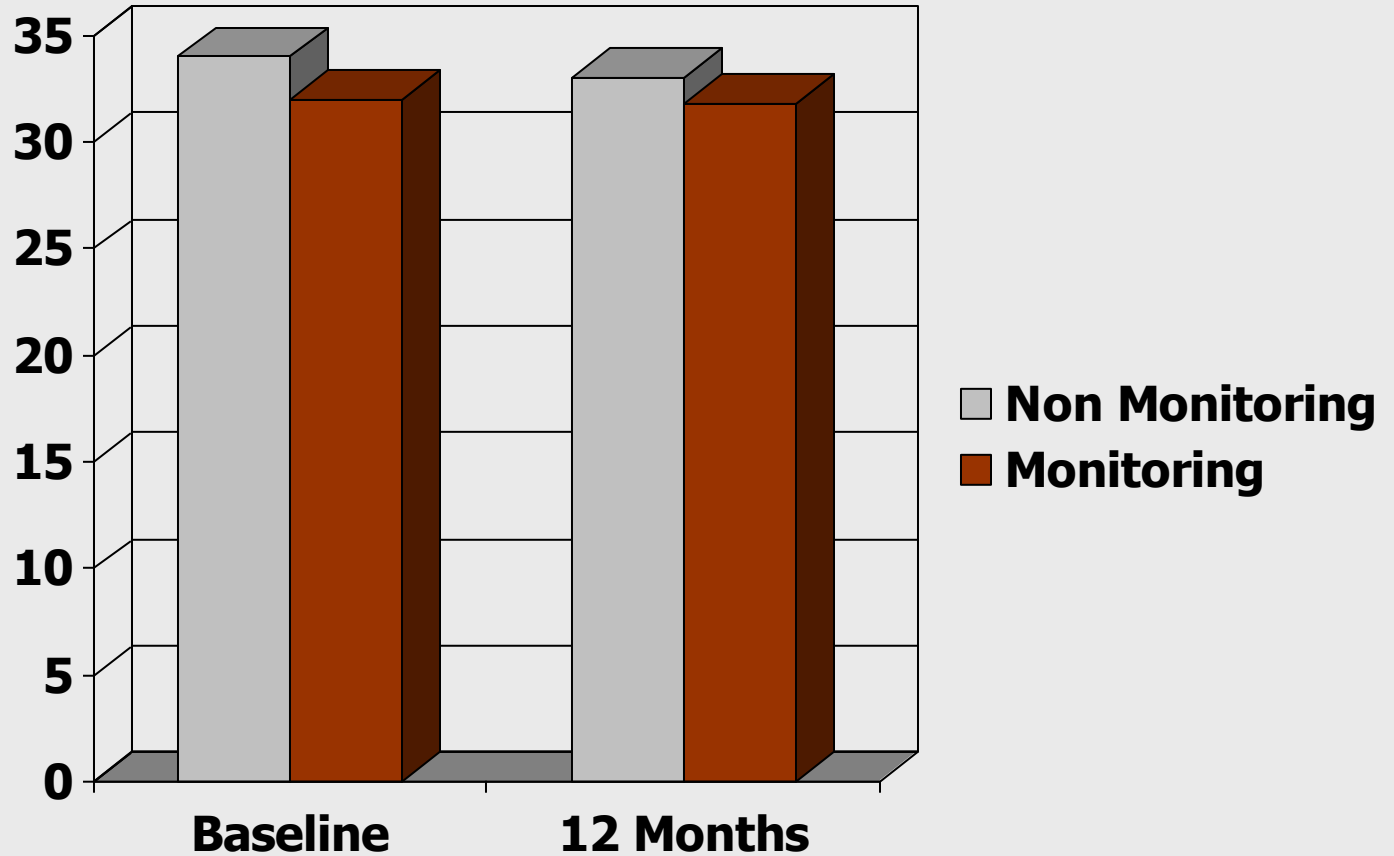
<sup>1</sup> All variables were scored on a 100 point scale and therefore the beta coefficient corresponds to the % change associated with monitoring



# Oral hypoglycaemic agents

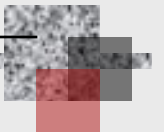


# Control Vs Monitoring BMI



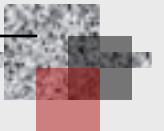
# Conclusions

- ◆ In this cohort of patients with newly diagnosed T2DM self-monitoring of blood glucose had no effect on HbA1c, hypoglycaemia, BMI, OHA usage
- ◆ SMBG was associated with a small [6%] increase in depression index scores



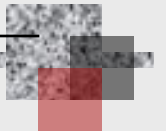
# Limitations

- ◆ Did not take into account patient preference
- ◆ No measurement of actions taken by monitoring group in response to SMBG readings



# Strengths

- ◆ Newly diagnosed T2DM patients
- ◆ High starting HbA1c [8.8 / 8.6%]
- ◆ High proportion of eligible patients randomised
- ◆ Low drop out rate [2.2%]



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