

Griffith University

**Leveraging online and in-pharmacy support to enhance weight loss:
a population based analysis**

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Introduction

The rate of excess body mass (overweight and obesity) is now considered at epidemic proportions in Australia, with over two thirds of adults and quarter of children considered overweight or obese. Excess body mass is a risk factor for a range of chronic diseases, including metabolic syndrome, type 2 diabetes mellitus, cardiovascular disease, non-alcoholic fatty liver disease and a range of cancers. Reducing excess body mass is therefore considered a key public health priority given the growing economic and social burden associated with overweight and obesity related disease.

Weight management strategies generally focus on energy restriction and/or altering macronutrient profiles, such as low fat or low carbohydrate, high protein or high fat diets. Examination of energy restricted diets indicate that they promote weight loss in the short term but that compliance contributes to prevent meaningful weight loss over medium to longer term time periods [1]. The inclusion of additional strategies to improve compliance is being investigated to enhance weight loss. Initial investigations indicate that the use of strategies to guide individuals with their weight loss is more effective than utilising diet education only, with Keogh et al finding the use of meal replacements over three months lead to a greater reduction in body mass in type 2 diabetics than the use of only a commercially available diet book in a community setting [2]. With the advent of the internet there is growing interest in the use of online tools and in-pharmacy support to augment tradition weight management programs for weight loss. The use of online tools in one study was found to enhance health and nutrition literacy [3]. Initial studies indicate that the benefits of using online tools are mixed. A study by O'Brien based in Australia found that diet quality improved significantly with the use of online tools and that higher diet quality was associated with greater weight loss [4]. In comparison, Brindal et al found that the inclusion of social networking features with the Total Wellbeing Diet did not lead to additive effects on weight reduction relative to a static control [5], which is consistent with other research [5].

Few programs combine the use of energy restricted dietary intake with the use of meal replacements, personalised pharmacy support and an online tool. Impromy™ is a weight management program that combines a CSIRO book with recipes based on the Total Wellbeing Diet alongside a commercial meal replacement and that uses in-pharmacy and online support to maximise user interaction.

The Impromy™ program has been running for just under 12 months. The aim of this report is to examine data collected on participants in their first 12 weeks on the program for an interim analysis on whether the use of online and pharmacy support has additional benefits to the use of the Total Wellbeing Diet or meal replacements on their own.

Methods

Participant data for the Impromy™ Program is collected in pharmacy and stored on the Pharmacy Guild's central server. Individuals enrol for the program with a pharmacy and health checks and testing are conducted on day 1, 4 weeks, 12 weeks, 26 weeks and 52 weeks, although participants are able to undertake health checks as often or as little as interested. The measures recorded include weight, blood pressure, cholesterol and glucose levels. A list of the field codes completed in the pharmacy is at Appendix 1.

Data from all participants was standardised longitudinally from their first visit and assigned a week number. Participants were included in the analysis if they had a baseline body mass measure and a follow up measure at week 4, week 8 or week 12. Duplicate values in any given week were averaged if there was less than 5% difference between the values otherwise the first value was maintained in the data set. With the aim of avoiding erroneous data we excluded individuals with weight values under 40kg or over 175kg or who displayed percentage changes from baseline that were two standard deviations from the average percentage change for a given time-point. All data was log transformed prior to analysis to permit the data to be analysed as a percentage. All analysis was undertaken using Graphpad Prism 6. Adjustments were made for baseline values and weight was used as a covariate for blood pressure, triglycerides and glucose.

For the Total Wellbeing Diet a search of EMBASE, PUBMED and MEDLINE was undertaken. Search terms included low carbohydrate, high fat diet, weight loss diets and high protein diet. Very low calorie diets were not included given they are designed as short term dietary interventions. Studies were included if they listed results up to 12 weeks from the start of the intervention. No limitations on study cohorts or the use of placebo or control diets were applied. Studies were only included if they referred to the dietary intervention by name in the paper.

Results

The results section provides summary data from the Impromy program and then from research on the CSIRO Total Wellbeing Diet to examine the effect of including in-pharmacy and online support to the use of the diet book.

Impromy™

Participants

- There were 3,814 individuals who had body mass recorded twice or more in the 12 week period after weighing in at registration.
- A total of 2,529 individuals had their age from this cohort had a recorded age (mean age 50±15 yrs; mean ±SD).

Weight

Table 1 details the weight loss in participants over 12 weeks on the Impromy™ program. Average weight loss at the end of 12 weeks was 7% with over 25% of individuals on the program losing greater than 10%.

Week		Week 0	Week 4	Week 8	Week 12
	N	3814	1828	1098	847
% loss in numbers from start			52	71	78
Mean absolute body mass by week of all participants (Kg)		93	92	91	89
% change in body mass from week 0 (mean change; 95% CI)			-3.2; -3.2 ± -3.1	-5.5; -5.4 ± -5.6	-7.0; -7.2 ± -6.8

Body mass index

The effect of Impromy™ on BMI over 12 weeks is characterised in Table 2. Similar to the effects of Impromy™ on body weight, there was a decrease in BMI over the course of 12 weeks, with an average decrease of 7% in BMI.

Week		Week 0	Week 4	Week 8	Week 12
	N	3814	1828	1098	847
% loss in numbers from start			52	71	78
Mean absolute body mass index by week of all participants (Kg/m ²)		34	34	34	34
% change in body mass index from week 0 (mean change; 95% CI)			-3.1; -3.2 ± -3.0	-5.5; -5.6 ± -5.5	-7.0; -7.3 ± -6.8

Glucose

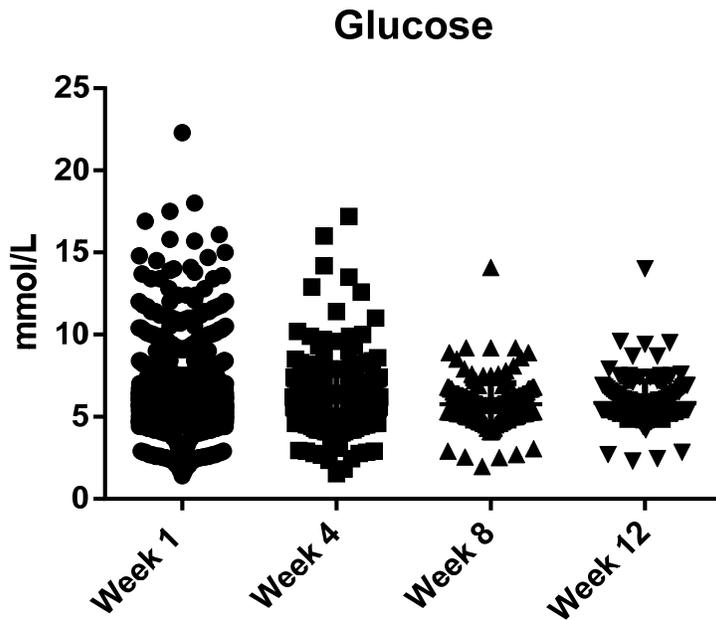
Table 3 characterises the change in blood glucose in participants at weeks 4, 8 and 12 while on the Impromy™ program. These data should be treated cautiously as there is no indication participants were fasted. This is reflected in the data showing no consistent increase or decrease over 12 weeks on the Impromy™ program.

Week		Week 0	Week 4	Week 8	Week 12
Total numbers	N	2559	367	185	152
% loss in numbers from start			86	93	94
Mean absolute blood glucose of all participants (mmol/L)		5.9	6.0	5.8	5.8
% change in glucose from week 0 (mean change; 95% CI)			2.7; -1.3 to 6.8	-3.2; -6.7 to 0.4	2.8; -3.4 to 9.3

mmol – millimole; L-litre, CI-confidence interval

Figure 1 displays the range of blood glucose values at each time point. The narrowing of the variation is suggestive that participants may have a reduction in blood glucose. However this needs to be confirmed in a larger cohort.

Figure 1: the mean and range of values of blood glucose over 12 weeks on Impromy™.

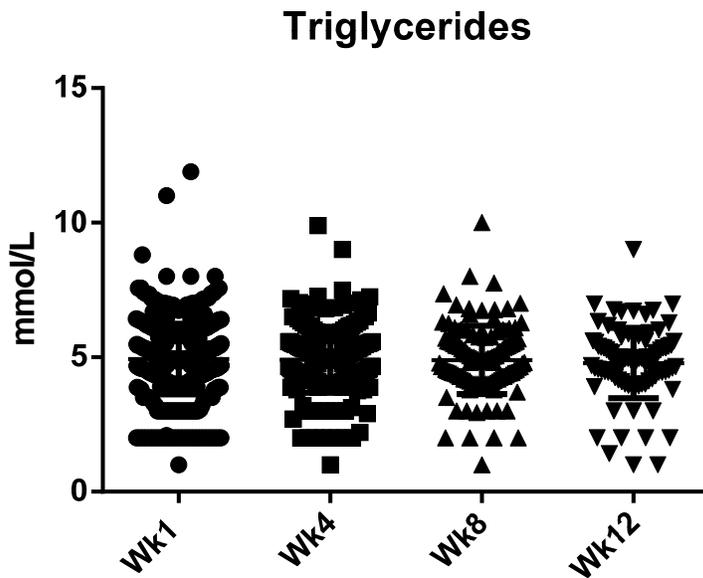


Triglycerides

The change in triglycerides over 12 weeks on the Impromy™ program is shown in Table 4. Given this is a random (not fasted) sample no comparison can be made to clinical studies with fasted samples. Figure 2 displays the variance in triglycerides at each time point.

Week		Week 0	Week 4	Week 8	Week 12
Total numbers	N	514	221	123	93
% loss in numbers from start			57	76	81
Mean absolute triglycerides of all participants (mmol/L)		4.9	4.9	4.9	4.8
% change in triglycerides from week 0 (mean change; 95% CI)			-0.9; -5.3 to 3.7	-2.2; -8.9 to 5.1	-7.2; -17 to 3.7

Figure 2: absolute values of triglycerides of individuals on the Improvy™ program at weeks 0, 8, and 12. No clinical differences were observed.

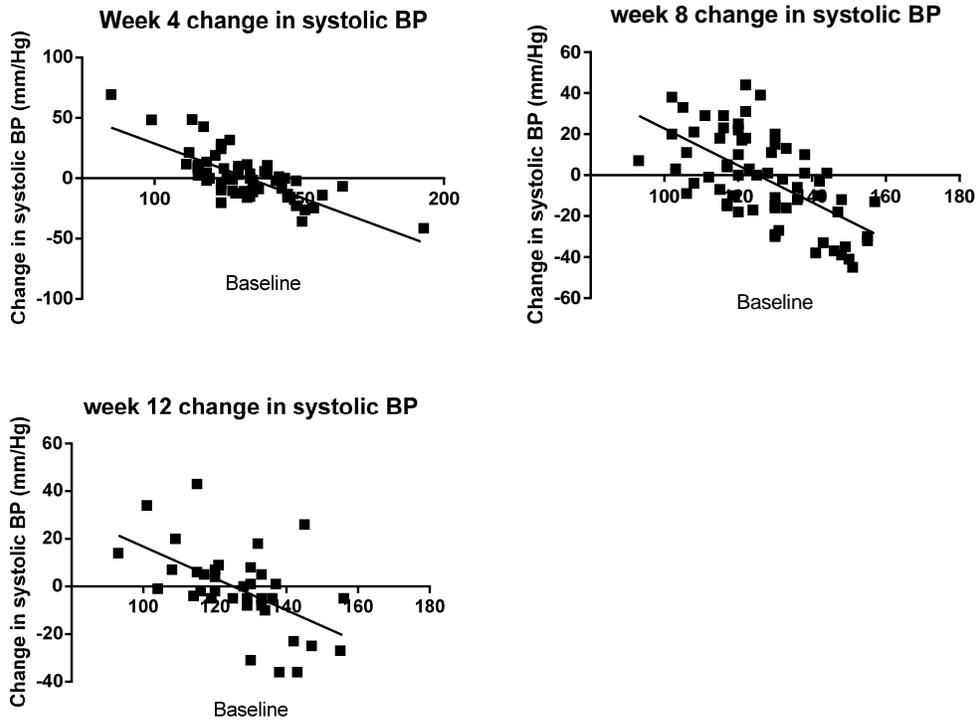


Systolic blood pressure

The change in systolic blood pressure over 12 weeks on the Improvy™ program is characterised in Table 5. Overall there was a reduction in blood pressure, however the number of participants with recorded blood pressure is low. Interestingly, when adjusting for the starting value, there is a clear trend for a reduction in systolic blood pressure for those with higher blood pressure on the Improvy™ program, although the data also suggest that those that have low blood pressure at entry experience an increase in systolic blood pressure (Figure 3a-c).

Week		Week 0	Week 4	Week 8	Week 12
Total numbers	N	544	232	135	106
% loss in numbers from start			-57	-75	-81
Mean absolute systolic blood pressure of participants included in analysis (mmol/L)		128 ± 16	124 ± 18	124 ± 16	126 ± 14
% change in systolic blood pressure from week 0 (mean change; 95% CI)			-4.4; -6.4 to -2.5	-2.0; -4.7 to -0.8	-1.4; -4.6 to 1.8

Figure 3a-c. The reduction in systolic blood pressure after 4 weeks on the Impromy™ program as a function of the baseline sample. This indicates that those with a higher systolic blood pressure at entry to the program have a reduction of blood pressure after four weeks but that those with normal systolic BP had an increase in systolic BP.

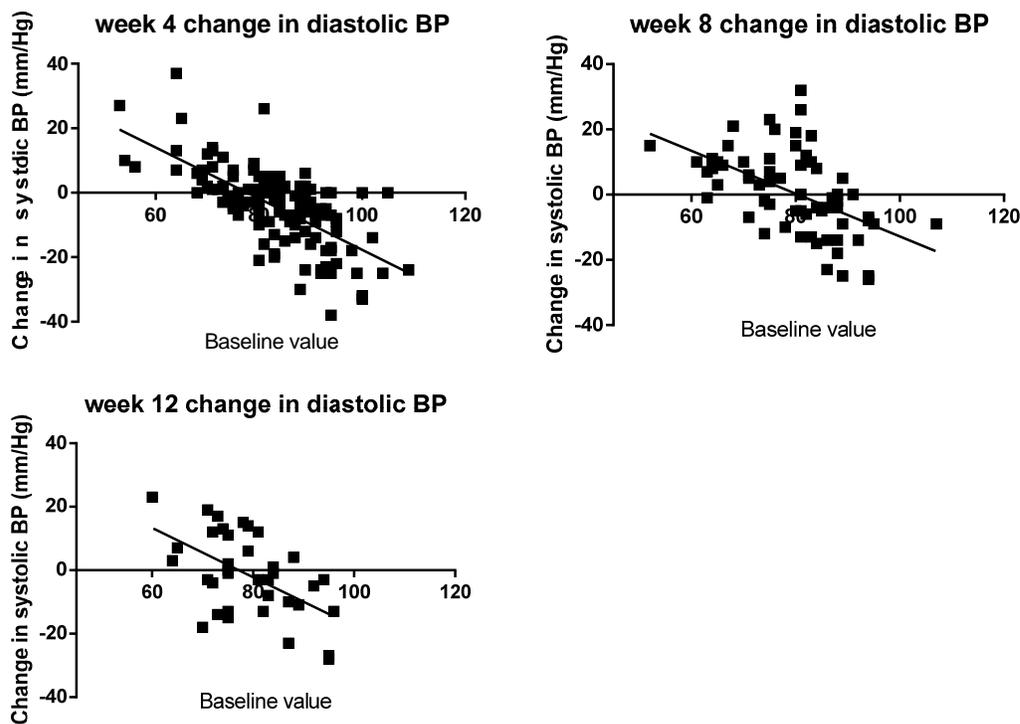


Diastolic Blood pressure

There was a non-linear reduction in average diastolic blood pressure over 12 weeks on the Impromy™ program, with a 3% reduction observed at week 4, a 0.4% reduction at week 8 and a 3.7% reduction observed at week 12 (Table 5). Consistent with the effects observed in systolic blood pressure, those with higher diastolic blood pressure had a greater reduction than those with normal blood pressure. Those at the 90th percentile (>94 mm Hg) had a 14% reduction in diastolic blood pressure compared to a 7% increase for those in the bottom 10th percentile (<68mm Hg) (Figure 6a-c)

Week		Week 0	Week 4	Week 8	Week 12
Total numbers	N	544	232	135	106
% loss in numbers from start			-57	-75	-81
Mean absolute diastolic blood pressure of participants included in analysis (mm/Hg)		81± 11	79 ± 10	79 ± 10	79 ± 11
% change in diastolic blood pressure from week 0 (mean change; 95% CI)			-2.9; -4.5 to -1.2	- 0.4; -3.1 to 2.3	-3.7; -7.7 to 0.4

Figure 4a-c: The effect of Impromy™ at weeks 4, 8 and 12 on diastolic blood pressure adjusted for each participant's diastolic value at baseline. Those with higher baseline values experience a reduction in diastolic pressure while those at normal or low levels experience an increase in diastolic blood pressure.



Total Wellbeing Diet

Four studies directly referring to the Total Wellbeing Diet* were located. Three of these studies had modifications to the program (inclusion of other lifestyle activities or meal replacements) while one study [5] broadened the program to include online and social media in an attempt to improve compliance and engagement to the program. The results from these studies are listed in Table 6. Overall these studies show an average 3.69% reduction (range 2.76% to 5%) in bodyweight over 8 to 12 weeks.

Table 6: Details of weight loss from published studies on the CSIRO diet book.

Author	Subjects	Intervention	Reduction in weight mean % \pm SD; or mean kg \pm SD/SEM	Comments
Moran	46 obese women undergoing IVF	Diet consistent with TWBD or education only (diet and lifestyle)	<u>52 days</u> TWBD = -3.8kg \pm 3.0 (4%) Control = -0.5kg \pm 1.2 (0.5%)	The TWBD was modified to include meal replacements
Khoo [6]	31 obese T2DM males	Low fat, high protein, reduced CHO (TWBD), or Low calorie diet (LCD)	<u>8 weeks</u> 5% TWBD 10% reduction on LCD	The low fat, high protein reduced carbohydrate diet was based on the TWBD.
Brindal [5]	8112 self-reported overweight or obese individuals	Information only; Supportive; Personalised-supportive	<u>12 weeks</u> Average 2.76% across all programs with no sig difference between groups (ITT) or completers 4%	
Keogh [2]	120 T2DM obese patients	TWBD; Meal replacement	<u>12 weeks</u> MR=5.3kg (5%); TWDB=2.7kg (3%)	MR group lost greater fat mass and had a greater reduction in HbA1C. Both groups had equal lowering of BP

T2DM-Type 2 diabetes mellitus; CHO-carbohydrate, GP-General practitioner; kg-kilogram; TWBD – Total Wellbeing Diet; MR-meal replacement

Conclusions

Analysis of the Pharmacy Guild data indicates that the inclusion of online and pharmacy support as used in Impromy™ has additional benefits for weight loss to the use of the Total Wellbeing Diet (both the traditional and online version) or a meal replacement individually.

A number of limitations need to be acknowledged, including that the Guild Data is community based data and not clinical trial data. As such, no adjustment for other lifestyle factors, such as physical activity or compliance can be undertaken. A strength to the data is that it is community and population based, suggesting that the reduction in weight observed in a cohort of over 3,000 individuals is representative of the benefits to the population.

While not in the ambit of the current report, a search of the literature of the effects of other weight management programs in Australia, including Weight Watchers, the Zone Diet, a meal replacement program (Celebrity Slim) and the Paleo Diet, provides promising evidence that Impromy's™ inclusion of pharmacy and online support may lead to a greater reduction in weight than the use of these programs in their traditional form (see Supplementary information)

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Supplementary information

There are a wide variety of programs that promote weight loss, with the more popular including Weight Watchers, the Zone Diet, Celebrity Slim and the Paleo diet. A list of studies reporting the effects of weight management programs available in Australia on body mass over 12 weeks, where possible, are reported in Table 6. These studies are not an exhaustive search of the literature and results may differ between population cohorts, such as obese diabetic and obese non diabetic individuals, whether other lifestyle interventions are utilised and the use of medications. It should be noted that there are few studies of the Paleo diet included as the benefits of this diet are often examined independent of weight loss, such that energy intake is matched to prevent a reduction in weight (see [7] and [8]).

The results listed in Supplementary Table 1 are from weight loss programs available in Australia and include average weight loss in kilograms and by percentage at 12 weeks. If data is not available at 12 weeks but there data is reported at eight weeks then this information is included.

The overall findings include:

- Of eight studies located Weight Watchers led to an average loss of 5.12% (range 4.37% to 5.80%) from baseline over 12 weeks.
- The Zone Diet and Paleo Diet showed a reduction of 4.65% and 6.1% from baseline respectively.
- Celebrity Slim was associated with a reduction in weight of 5%.

Supplementary Table 1: Details of weight loss from the Weight Watchers, Zone Diet, Paleo Diet and Celebrity Slim.

Author	Subjects	Intervention	Reduction in weight mean % \pm SD; or mean kg \pm SD/SEM	Comments
Weight Watchers				
Milsom [9]	132 obese individuals	Weight Watchers; High fibre diet	<u>12 weeks</u> Weight Watchers $-4.37 \pm 3.71\%$	1.9% reduction in systolic BP and a 1.5% reduction in diastolic BP
Pinto [10]	141 overweight or obese adults	Weight Watchers (WW); Behavioural treatment (BT); WW+BT	<u>12 Weeks</u> Weight Watchers $\sim -5\%$ BT $\sim -4\%$ WW+BT $\sim -4\%$	% difference not reported and estimated from paper No blood pressure values
Jolly K [11]	740 obese individuals	Choice of: Weight Watchers; Slimming world; Rosemary Conley; Group-based; GP-advised; Pharmacy-advised	<u>12 Weeks</u> Weight Watchers = -5.15kg ($\sim 6\%$)	Percentage changes are not recorded in the paper but are an estimate. No blood pressure values reported
Johnstone CA [12]	292 overweight or obese individuals	Weight watchers (WW) Self-help (information)	<u>12 weeks</u> Weight watchers $\sim -5\%$ Self-help $\sim 1\%$	% difference not reported and estimated from paper No blood pressure values reported The WW group were provided with three ways to access the program,

				including weekly meetings; WW mobile application; and WW online tools. Participants using all three had a greater reduction in weight than participants only using one mode.
Madigan [9]	3290 overweight / obese individuals	Weight Watchers Other diets	<u>12 weeks</u> Weight Watchers -4.2kg	The study does not report baseline weight but a BMI of 35kg/m ² .
Heshka[13]	423 overweight / obese individuals	Weight Watchers Control	<u>12 Weeks</u> ~ -4.5% reduction in weight	The percentage reduction from baseline is inferred from data in the paper.
Morgan [14]	300 overweight or obese individuals	Weight Watchers Other diets	<u>8 Weeks</u> Weight Watchers ~ -5.8%	The percentage reduction from baseline is inferred from data in the paper.
Truby [15]	210 overweight and obese adults	Weight Watchers	<u>8 Weeks</u> Weight Watchers -5.1% ± 3.5	Those in the Weight Watchers group had a 2.8% decrease in systolic BP and a 5.1% decrease in diastolic BP
Zone Diet				
Mcauley [16]	96 overweight women with T2DM	High CHO, high fibre diet; Zone Diet.	<u>8 Weeks</u> High CHO -4.5kg (~ -4.4%) Zone diet ~ -5.4kg (~ -5.8%)	% difference not reported and estimated from paper
Gardner [17]	311 overweight or obese individuals		<u>12 Weeks</u> Zone ~ -3.5%	% difference not reported and estimated from paper
Paleo diet				
Jonsson	13 overweight or	Paleo diet;	<u>12 Weeks</u>	% difference not reported and estimated

T[18]	obese individuals with T2DM	Diabetes diet (AHA).	Paleo diet ~ -6.1% Diabetes diet ~ -4.3%	from paper
Celebrity Slim				
Keogh [2]	120 T2DM obese patients	TWBD; Celebrity Slim	<u>12 weeks</u> Celebrity Slim =5.3kg (5%); TWDB=2.7kg (3%)	Celebrity Slim group lost greater fat mass and had a greater reduction in HbA1C. Both groups had equal lowering of BP