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Predictors for misreporting sodium and potassium intakes by overweight and obese participants in a food-based clinical trial: implications for practice

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Predictors for misreporting sodium and potassium intakes by overweight and obese participants in a food-based clinical trial: implications for practice

Abstract

This study compared self-reported sodium and potassium intakes with urinary biomarkers and identified predictive factors. Secondary analysis of the 3-month intensive phase of the HealthTrack study with control (C), interdisciplinary intervention (I), intervention plus 30 g walnuts/day (IW) arms (n = 149). Dietary data was derived from diet history (DH) interviews and biomarker measures from urine. Urine-derived sodium (all, p = 0.000) and potassium (C: p = 0.011; I: p = 0.000; IW: p = 0.004) measures were significantly greater than self-reported intakes over the three months. Multiple linear regression showed body weight at baseline, body mass index (BMI) at baseline, and combined BMI at baseline and DH interviewer significantly negatively predicted the differences in sodium intake and excretion for C (β = −21.226, p = 0.016), I (β = −106.140, p = 0.002) and IW (F (9.530, 2df), p = 0.000), respectively. Where intakes of sodium and potassium are of interest in a trial, both reported intake and urinary biomarker measures are recommended.

Disciplines
Medicine and Health Sciences

1 **Predictors for misreporting sodium and potassium intakes by overweight and obese**

2 **participants in a food-based clinical trial: Implications for practice**

3 **Running title**: Predictors for misreporting sodium and potassium intakes

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15   **Abstract**

16   This study compared self-reported sodium and potassium intakes with urinary biomarkers

17   and identified predictive factors. Secondary analysis of the 3-month intensive phase of the

18   HealthTrack study with control (*C*), interdisciplinary intervention (*I*), intervention plus 30g

19   walnuts/day (*IW*) arms (n=149). Dietary data was derived from diet history (DH) interviews

20   and biomarker measures from urine. Urine-derived sodium (all, p=0.000) and potassium (*C*:

21   p=0.011; *I*: p=0.000; *IW*: p=0.004) measures were significantly greater than self-reported

22   intakes over the three months. Multiple linear regression showed body weight at baseline,

23   body mass index (BMI) at baseline, and combined BMI and DH interviewer at baseline

24   significantly negatively predicted the difference in sodium intake and excretion for *C* (β= -

25   21.226, p = 0.016), *I* (β= -106.140, p = 0.002) and *IW* (F (9.530, 2df), p=0.000) ,

26   respectively. Where intakes of sodium and potassium are of interest in a trial, both reported

27   and urinary biomarker measures are recommended.

28

Introduction

Well-designed randomised controlled trials (RCTs) provide the highest level of evidence for developing dietary recommendations in nutrition[1]. Where food-based trials are undertaken, the relationship between foods and nutrients needs to be considered to reflect the accuracy of reported food intakes. Moreover, the measurement of self-reported dietary intake data appears to be influenced by the dietary intervention itself. This intervention related bias may impact on the interpretation of the findings[2, 3]. The aim of this study was to compare estimates of intake for dietary sodium and potassium with biomarker measures for urinary excretion of sodium and potassium. A secondary aim was to determine factors associated with differences between the measures in the context of a RCT for weight loss.

Methods

The present study is a secondary analysis of the 3-month intensive phase of the HealthTrack study (ANZCTRN #12614000581662) for weight loss, involving three arms: a control (*C*), a novel interdisciplinary lifestyle intervention (*I*) and intervention plus 30g walnuts/day (*IW*). All participants provided written informed consent. Detailed study protocols (4) and primary results (5) are described elsewhere. Detailed methods of data handling are provided in the **Supplementary Information**. In brief, dietary intakes reflecting usual weekly food consumption over the previous three-month period was collected using a diet history (DH) interview at baseline and 3 months. The plausibility of self-reported dietary intake has been reported elsewhere[6]. Overweight and obese participants (Body Mass Index (BMI) 25-40kg/m^2) collected 24-hour urine samples at baseline and 3 months. The incomplete urine samples (<500mL or creatinine ratio outside 0.6-1.4) and participants taking diuretics were excluded. Urine-derived intakes were calculated. The usual urine-derived intake of sodium and potassium in the three month intensive phase of the HealthTrack was calculated using the

53 Multiple Source Method(7). Bland-Altman plots were developed for self-reported vs. urinary

54 measures and multiple linear regression used to determine predictive factors.

55 **Results**

56 A total of 149 participants were included in this analysis (**Supplementary Figure 1**). The

57 values of age and BMI were 44.2±7.6 years and 32.0±4.2 kg/m^2, respectively; and 69.1% of

58 participants were female. Participant data by study arms is presented in **Table 1**.

59 Median urine-derived sodium and potassium intakes were significantly greater than median

60 self-reported intakes in all arms at three months (sodium: *C*: p=0.000; *I*: p=0.000; *IW*:

61 p=0.000; potassium: *C*: p=0.011; *I*: p=0.000; *IW*: p=0.004). Correlations between self-

62 reported and urine-derived sodium measures were r = 0.213 (p=0.140) for *C*, r=0.146

63 (p=0.340) for *I* and r=0.298 (p=0.026) for *IW*. Correlations between potassium measures

64 were r=0.188 (p=0.200) for *C*, r=0.597 (p=0.000) for *I* and r=0.350 (p=0.008) for *IW*.

65 Bland-Altman plots demonstrated participants in all the arms generally underreported their

66 sodium and potassium intakes compared with urinary measures over the three months. The

67 range between the upper and lower limits of agreements for sodium and potassium intakes

68 was wide for all study arms. For sodium, in *I* the underestimation was greater at higher

69 intakes (**Figure 1**A), whereas for *IW* underestimation was less at higher intakes (**Figure 1B**).

70 The differences in estimated potassium intakes during the three months between self-reported

71 and urine-derived intakes were fairly consistent for all study arms.

72 The regression model established that body weight at baseline significantly predicted the

73 difference in sodium intakes during three months for *C* (β=-21.226, t=-2.511, p=0.016), but

74 BMI at baseline (β=-106.140, t= -3.258, P = 0.002) for *I*. BMI at baseline (β=-0.017, t=-

75 3.654, p=0.001) and the DH interviewer (β=-0.019, t=-2.382, p=0.021) significantly predicted

76   the difference in sodium intakes between self-reported and urine-derived data at three months

77   for *IW*. The model was significant, (F (9.530, 2df), p=0.000) explaining 26% variability of

78   the difference between sodium measurements for *IW*. There were no identified predictors for

79   the difference in potassium intakes between self-reported and urine-derived data for all arms.

80   **Discussion**

81   The present analysis was aimed to determine the specific observed bias related to intakes of

82   sodium and potassium. As both sodium and potassium are fairly ubiquitous in the food

83   supply, it was expected that participants in all study arms underreported intakes. The finding

84   for sodium intakes are consistent with other research (3), but in this study, the under-

85   reporting of potassium intakes compared to biomarker values was not anticipated (3). This

86   discrepancy may be attributed to differences in dietary advice in the intervention arms,

87   focused on reduced sodium intakes (3), versus energy reductions in the HealthTrack study

88   overall. Additionally, while potassium is mainly sourced from consumed foods, sodium is

89   also added to foods, particularly for processed and convenience foods. The results also

90   suggested that the intra-individual variances of urine-derived sodium intake were greater than

91   those for potassium intake. Thus a greater underreporting of sodium from DH interviews

92   compared to potassium is likely. This aligns with literature previously demonstrating the

93   challenges in estimation of sodium intake (8). It confirms that biomarkers and/or additional

94   dietary assessment tools may be required to strengthen the quality of data in food-based

95   RCTs if there is a concurrent interest in nutrients such as sodium and potassium.

96   The findings of this study also confirm that dietary interventions themselves may influence

97   accurate assessment of dietary intake data (2, 3), particularly using DH interviews. One of the

98   main activities of individualised dietary advice provided by dietitians is goal setting(9), and

99   in this case losing weight was the primary goal. Anecdotal evidence suggests that those who

100 did not achieve their weight loss goals required dietitians to ask more probing questions

101 during the DH interviews. Additionally, the proportions of female and overweight and obese

102 participants were high in the present sample, who tended to misreport dietary intake(10).

103 Thus, participants may be more conscious of their body weights measurements, which in turn

104 may influence their dietary intake reporting.

105 In conclusion, dietary advice needs to be provided in terms of foods but reporting of food

106 intake is inaccurate, especially with respect to sodium which can be added to food. Where

107 intakes of sodium and potassium are of interest in a trial, both reported measures and urinary

108 biomarkers are required to identify reported food sources, enhance advice provision and to

109 ensure the accuracy of nutrient intake estimates.

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147   *Figure legends*

148   Figure 1A: Bland-Altman plot for assessing bias between self-reported dietary intake and

149   urine derived intake for sodium intake for intervention arm during 3 months of intensive

150   phase of the HealthTrack study (secondary analysis cohort)

151   Figure 1B: Bland-Altman plot for assessing bias between self-reported dietary intake and

152   urine derived intake for Log10 value of sodium intake for intervention + walnut arm during 3

153   months of intensive phase of the HealthTrack study (secondary analysis cohort)

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Table 1: Demographic characteristics, dietary nutrient intakes and biomarkers by arms during 3 months of intensive phase of the

HealthTrack study (secondary analysis cohort)

	Control (n=48)	Intervention (n=45)	Intervention + Walnuts (n=56)	p value
Age (y)[1]	44.5±7.3	45.8±6.5	42.8±8.5	0.128[2]
Gender n (%)				0.893[3]
Male	16 (33.3)	13 (28.9)	17 (30.4)	
Female	32 (66.7)	32 (71.1)	39 (69.6)	
Levels of education n (%)				0.118[3]
No school certificate or other qualifications	3 (6.3)	2 (4.4)	0 (0)	
School or intermediate certificate (or equivalent)	0 (0)	5 (11.1)	1 (1.8)	
Higher school or leaving certificate (or equivalent)	3 (6.3)	2 (4.4)	4 (7.1)	

Trade/apprenticeship (e.g. hairdresser, chef)	4 (8.3)	5 (11.1)	3 (5.4)	
Certificate/diploma (e.g. child care, technician)	13 (27.1)	6 (13.3)	18 (32.1)	
University degree	10 (20.8)	11 (24.4)	20 (35.7)	
Post graduate degree	15 (31.3)	14 (31.3)	10 (17.9)	
Body weight (kg)[1]				
At baseline	90.4±16.8	91.0±15.9	90.2±15.7	0.963[2]
At 3 months	89.1±16.7	87.8±15.8	87.4±15.0	0.848[2]
BMI (kg/m^2)[1]				
At baseline	32.3±4.2	32.1±4.1	31.8±4.3	0.888[2]
At 3 months	31.8±4.2	30.9±4.3	30.9±4.3	0.515[2]
Waist circumference (cm)[1]				
At baseline	104.0±13.6	102.8±11.1	102.3±12.2	0.776[2]
At 3 months	101.3±14.0	99.2±12.5	98.2±11.9	0.466[2]
Energy intake (kJ/d)[4]				

At baseline	8612.4 (7152.4 – 11021.7)	9165.0 (7820.4 – 11636.6)	9208.7 (7337.7 – 10720.4)	0.510[5]
During 3 months	7337.4 (6660.9 – 8972.0)	6635.6 (5933.0 – 7614.3)	7252.5 (6310.4 – 8821.1)	0.014[5]
Estimated energy requirement(kJ/d)[4]	8229.7 (7243.3 – 9600.4)	8285.4 (7479.7 – 9446.5)	8276.8 (7544.0 – 9818.6)	0.946[5]
Dietary sodium intake (mg/d)[4]				
At baseline	2008.6 (1557.7 – 2754.1)	2587.6 (1990.2 – 3014.4)	2634.9 (1964.5 – 3200.3)	0.120[5]
During 3 months	2060.4 (1566.5 – 2464.2)	1717.7 (1393.6 – 2064.9)	1703.1 (1418.8 – 2182.6)	0.054[5]
Dietary potassium intake (mg/d)[4]				
At baseline	3792.4 (3125.3 – 4666.6)	3821.0 (3304.7 – 4569.9)	3684.1 (3077.7 – 4317.0)	0.464[5]
During 3 months	3608.5 (2979.9 – 4224.0)	3320.2 (2990.2 – 3741.6)	3578.2 (3019.4 – 4153.1)	0.336[5]
Urinary sodium excretion (mg/d)[4]				
At baseline	3757.6 (2701.2 – 4981.1)	3450.0 (2527.3 – 4573.3)	4011.6 (3162.5 – 5141.6)	0.223[5]
At 3 months	3182.6 (2300.0 – 4366.0)	3102.3 (2326.7 – 4787.2)	3035.5 (2139.5 – 3744.2)	0.431[5]
Urine-derived sodium intake during 3 months (mg/d)[4,6]	3759.0 (3142.2 – 4176.6)	3551.4 (2999.8 – 4186.0)	3653.2 (3211.2 – 4151.6)	0.819[5]
Intra-individual variance(mg/d)[6]	3.60	1.37	0.34	-
Urinary potassium excretion (mg/d)[4]				

At baseline	4153.2 (3013.6 – 5356.2)	3748.1 (3393.5 – 4533.1)	4001.3 (2773.1 – 5267.5)	0.588[5]
At 3 month	3570.8 (3152.9 – 4457.1)	3798.7 (3064.3 – 4406.5)	4077.3 (2139.5 – 3744.2)	0.779[5]
Urine-derived potassium intake during 3 months (mg/d)[4,6]	4015.3 (3415.2 – 4642.0)	3962.3 (3501.4 – 4388.4)	3803.6 (3322.8 – 4658.5)	0.858[5]
Intra-individual variance(mg/d)[6]	0.12	0.01	0.07	-

157 [1] Data presented as mean ± SD

158 [2] Derived by one-way analysis of variance between arms

159 [3] Derived by Pearson's chi-square test for differences in portions between arms

160 [4] Data presented as median (interquartile range)

161 [5] Derived by Kruskal-Wallis H test between arms

162 [6] Derived from 24-h urinary data calculated by the Multiple Source Method(7), by computing 24-h urinary data at baseline and at 3 months
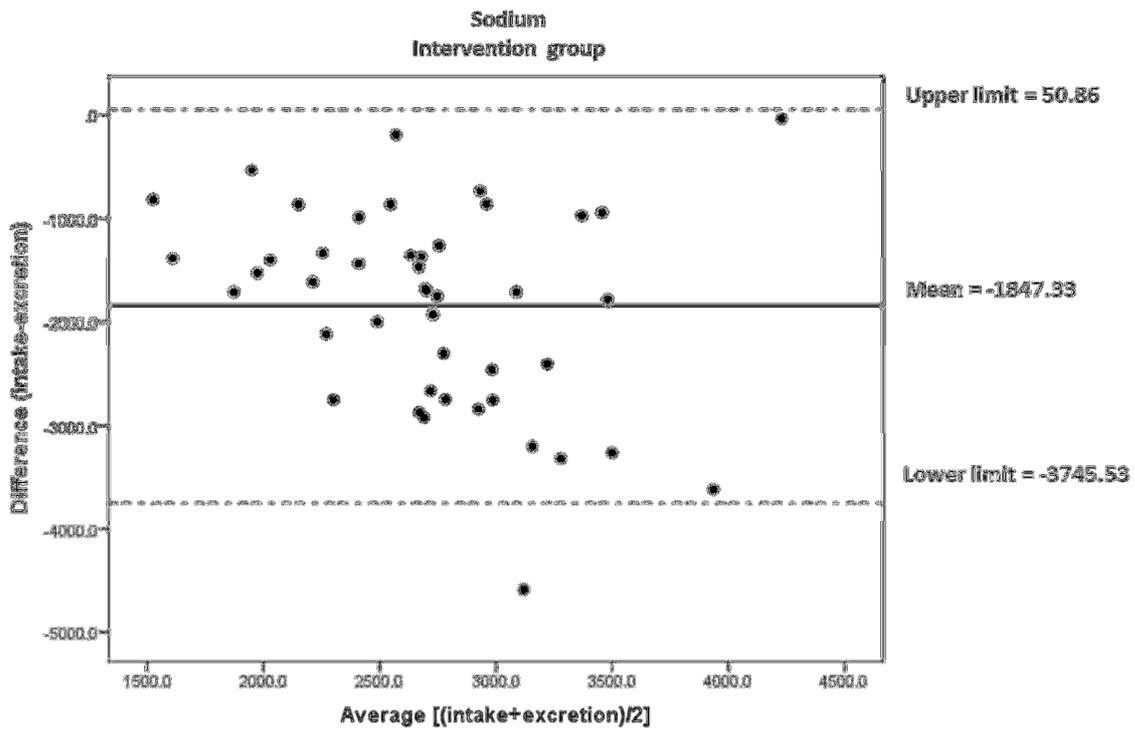
163

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Figure 1A: Bland-Altman plot for assessing bias between self-reported dietary intake and urine derived intake for sodium intake for intervention arm during 3 months of intensive phase of the HealthTrack study (secondary analysis cohort) [1].

[1] Solid line represented the mean difference; dotted lines represented upper and lower limits of agreement (mean ± 1.96 SDs)
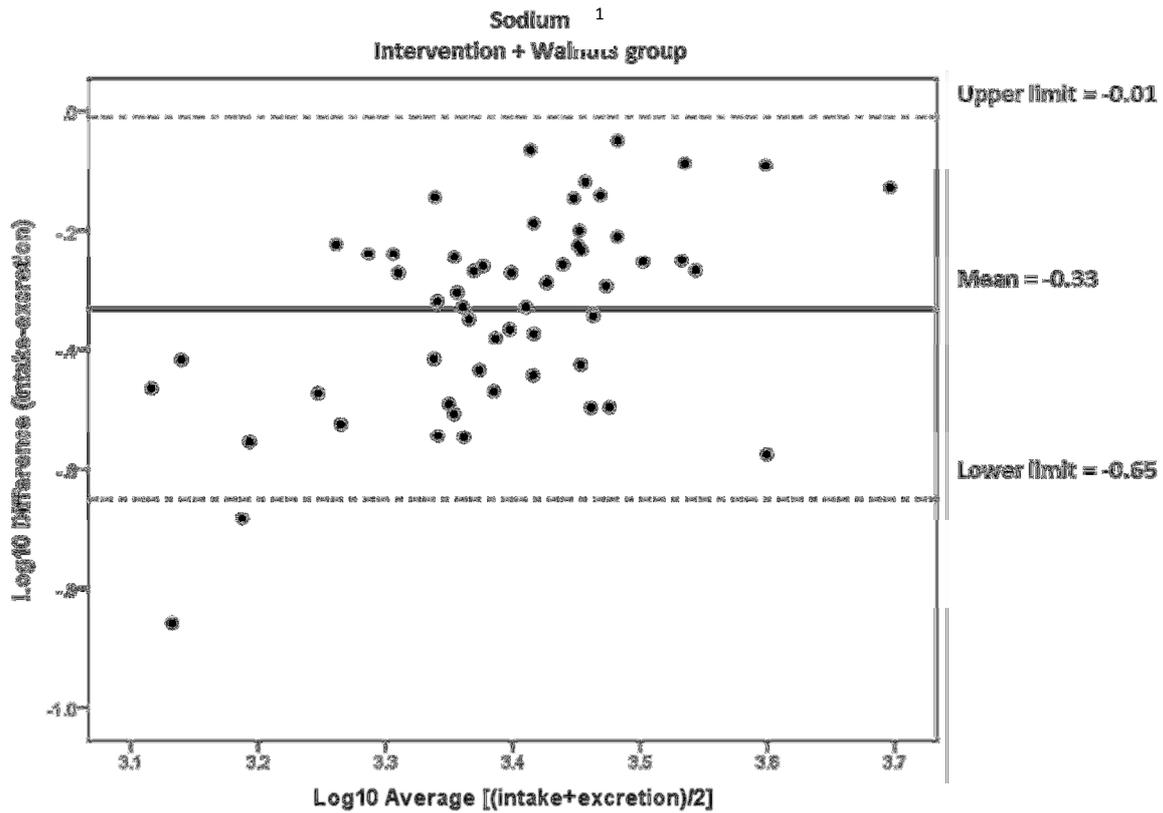
Figure 1B: Bland-Altman plot for assessing bias between self-reported dietary intake and urine derived intake for Log10 value of sodium intake for intervention + walnut arm during 3 months of intensive phase of the HealthTrack study (secondary analysis cohort)[1].

[1] Solid line represented the mean difference; dotted lines represented upper and lower limits of agreement (mean ± 1.96 SDs)

Supplementary information - Detailed methods

The HealthTrack study

The present study is a secondary analysis of the 3-month intensive phase of the HealthTrack study. Detailed study protocols (4) and primary results (5) are described elsewhere. In brief, the HealthTrack study was a 12-month randomised controlled trial (Australian and New Zealand Clinical Trial Registry, ANZCTRN 12614000581662). Ethics approval for the HealthTrack study was obtained from the University of Wollongong/Illawarra Shoalhaven Local Health District Human Research Ethics Committee (HE13/189). The aim of the trial was to test the effects of a novel interdisciplinary lifestyle intervention delivered by a dietitian compared with usual care delivered by a nurse. The primary outcomes was weight loss in overweight and obese adults. There were three arms involved in the study, a control arm providing usual care based on the Australian Guide to Health Eating (*C*) (11), an intervention arm receiving interdisciplinary intervention delivered by individualised dietary advice (*I*) and a third arm receiving the intervention plus 30g walnuts per day (*IW*). A computer-generated randomisation sequence was applied for randomization by an independent investigator. Participants and DH interviewers were blinded to the randomised groups. Individualised dietary advice in the intervention groups was achieved by personalised target requirements and participants' usual food habits. Estimated energy requirements were calculated using the Mifflin-St Jeor equation (12). Recruited participants were aged 25-54 years, with a Body Mass Index (BMI) of 25-40kg/m^2, and residents of the Illawarra region. Participants who were unable to communicate in the English language, had an impaired ability to participate in the study, other medical conditions thought to limit survival to 1 year, suffered from immunodeficiency, reported illegal drug use or regular alcohol intake associated with alcoholism (>50 g/day), or difficulties or major impediments to participating in components of the study were excluded. Participants' level of education was self-reported

during a screening survey. Body weight, height, waist circumference were measured by using standard procedures (4). BMI was also calculated.

Urine derived dietary intake

Participants were asked to collect 24-hour urine samples to assess sodium and potassium excretion at baseline and 3 months. Detailed instructions were provided by Accredited Practising Dietitians (APDs) and standard plastic containers were distributed to all participants. Participants were instructed to discard the first urine of the day and collect the rest over a 24 hour period. The collected samples were stored at 2°C to 8°C by Southern IML Pathology. The total volume of urine was measured, recorded and indirect ion-specific electrodes were used to determine sodium and potassium concentrations. The Jaffe reaction colorimetric method was applied to determine creatinine concentration (13). Participants who were taking diuretics and those with incomplete urine samples were excluded from analyses. Total urine volume of a sample less than 500 mL (14) and/or a creatinine ratio out of range of 0.6-1.4(15) was used to identify incomplete urine samples. The creatinine ratio was calculated as observed creatinine excretion divided by expected creatinine excretion, with expected creatinine excretion estimated using the Joossens & Geboers algorithm (expected creatinine excretion $=$ body weight (kg) $*$ 24 for males or 21 for females) (15). In the case that body weight was not collected, the sample was discarded if the creatinine of the sample was ≤6.0 mmol/day and the urine volume was <1000mL/day(16). The overall recovery rates of urinary sodium and potassium are reported to be 86% and 77%, respectively (17, 18). Thus, the 24-hour urine-derived intakes of sodium and potassium were the result of 24-hour urinary sodium and potassium divided by 0.86 and 0.77, respectively.

Self-reported dietary intakes

Dietary intake data reflecting usual weekly food consumption at baseline and at three months was collected using a DH interview performed by APDs, conducted between May 2014 and July 2015. The dietary intake data collection protocol was validated previously (19). Participants were asked to recall their usual intake over the past three-month period at the three month time point. A food checklist was used to assess commonly omitted food items during the interviews. Collected food intake data was coded to FoodWorks Professional nutrient analysis software (Xyris, Springhill QLD, Australia, Version 7, 2007) supported by the AUSNUT 2007 food composition database (20). The plausibility of self-reported dietary intake has been examined and reported elsewhere(6).

Statistical methods

The usual urine-derived intake of sodium and potassium in the three month intensive phase of the HealthTrack were calculated by using the Multiple Source Method (7). To account for within-person variability of intakes, the 24-h urine-derived intakes of sodium and potassium at baseline and three months were computed. Statistical analyses were performed using IBM SPSS Statistics (version 21.0, IBM Corp, Chicago IL, 2012). Normally distributed data was presented as mean and standard deviation and as median and interquartile range for skewed data. To assess difference in demographic characteristics, dietary nutrient intakes and biomarkers between study arms, one-way analysis of variance was used for normally distributed data and Kruskal-Wallis H test for nonparametric data. The post-hoc test was used to identify where the differences were within arms. A Pearson's chi-square test was applied to compare differences in the proportion of gender, levels of education and DH interviewers between arms. The Wilcoxon signed rank test was conducted to assess the difference in self-reported dietary intake and urine-derived intake of sodium and potassium between baseline and three months in each arm, and Spearman's correlation was used to examine the relationship between self-reported dietary intake and urine-derived intake of sodium and
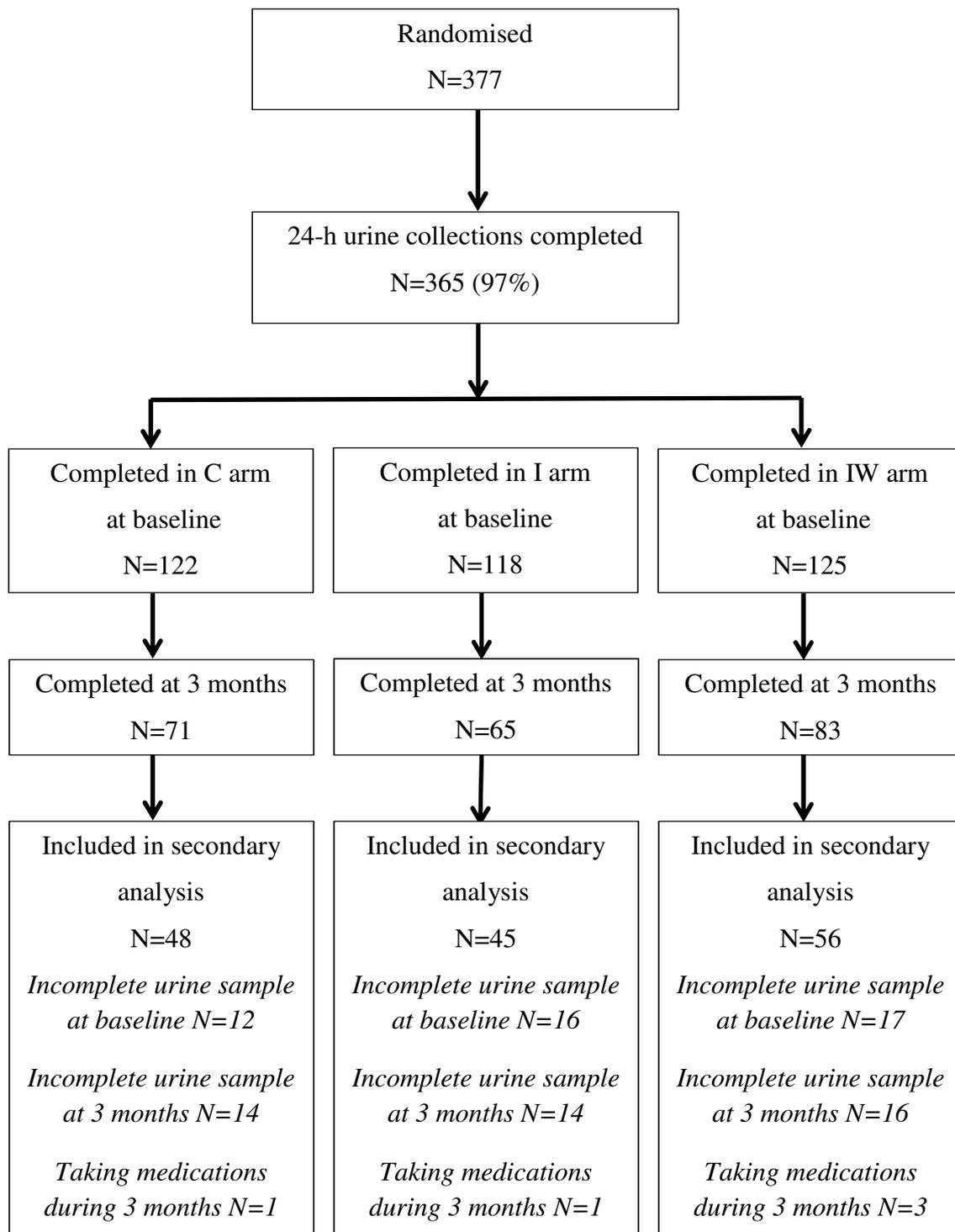
potassium. Bland-Altman plots (21) were used to investigate relative agreement between self-reported dietary intakes and urine-derived intakes by plotting the difference of intake of each participant against the mean of both measurements. The 95% limits of agreement in Bland-Altman plots were calculated by the mean difference ± 1.96 * SD. Stepwise multiple linear regression was used to identify the predictors of the difference between dietary and urinary sodium and potassium measures. Covariates included age (y), gender, levels of education, body weight at baseline (kg), BMI at baseline (kg/m^2), waist circumference at baseline (cm), body weight change at 3 months (kg) and DH interviewers who conducted DH interview at 3 months. Normality, linearity, multicollinearity and homoscedasticity of the identified models were assessed to ensure there were no violations of assumptions. The distribution of differences between self-reported and urine-derived intakes of sodium and potassium were estimated prior to performing Bland-Altman plots and stepwise multiple linear regression analysis using the Shapiro-Wilk test. A logarithmic transformation of original data was conducted for differences that were not normally distributed for the Bland-Altman plots and stepwise multiple linear regression analysis. Statistical significance was determined as a two-sided P values less than 0.05.

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                    ┌─────────────────────────┐
                    │        Randomised        │
                    │          N=377           │
                    └─────────────────────────┘
                                 │
                                 ▼
                    ┌─────────────────────────┐
                    │ 24-h urine collections   │
                    │       completed          │
                    │       N=365 (97%)        │
                    └─────────────────────────┘
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Completed in C arm at baseline N=122	Completed in I arm at baseline N=118	Completed in IW arm at baseline N=125
Completed at 3 months N=71	Completed at 3 months N=65	Completed at 3 months N=83
Included in secondary analysis N=48 *Incomplete urine sample at baseline N=12* *Incomplete urine sample at 3 months N=14* *Taking medications during 3 months N=1*	Included in secondary analysis N=45 *Incomplete urine sample at baseline N=16* *Incomplete urine sample at 3 months N=14* *Taking medications during 3 months N=1*	Included in secondary analysis N=56 *Incomplete urine sample at baseline N=17* *Incomplete urine sample at 3 months N=16* *Taking medications during 3 months N=3*

Supplementary Figure1: Participant flow of urinary collection and analyses in the HealthTrack study