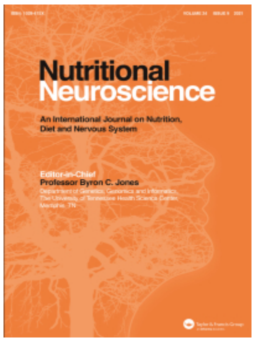

Nutritional Neuroscience
An International Journal on Nutrition, Diet and Nervous System

ISSN: 1028-415X (Print) 1476-8305 (Online) Journal homepage: www.tandfonline.com/journals/ynns20

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NUTRITIONAL NEUROSCIENCE
https://doi.org/10.1080/1028415X.2026.2635535

The effect of prebiotic intervention foods on caregiver-reported infant sleep and caregiver sleep quality during complementary feeding-secondary analysis of a randomized control trial

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ABSTRACT

Background: Sleep is essential for infant health and cognitive development. Poor sleep increases the risk of childhood obesity and weakens immune health. Infant sleep is a major concern for parents, as disruptions can impact parental sleep and overall well-being, leading to various negative consequences. Prebiotic foods introduced during the complementary feeding period may potentially improve infant sleep and, consequently, parental sleep. However, to our knowledge, no studies have yet explored this relationship.

Methods: As a secondary outcome analysis of a three-arm parallel randomized control trial (ACTRN12620000026921), this paper compared the effects of kūmara (K group, n = 93) or kūmara with added resistant starch (K^+ group, n = 93) to a control group (n = 95) on infant sleep and caregiver sleep quality during the first four months of complementary feeding. Infant and caregiver sleep were subjectively assessed at baseline (prior to solids), and at two (Complementary Feeding 2, CF2) and four (Complementary Feeding 4, CF4) months post-introduction to solids, using the caregiver-reported Brief Infant Sleep Questionnaire (BISQ) and Patient-Reported Outcomes Measurement Information System (PROMIS®) scales for Sleep Disturbance and Sleep-Related Impairment, respectively.

Results: Compared to the control group, infants in the K group had significantly less nocturnal wakefulness (8.4 min, $p = 0.023$) at CF4. The K^+ group showed a near-significant increase in daytime sleep (11.4 min, $p = 0.053$) but also trends toward more reports of problematic nighttime sleep at CF2. Caregiver sleep outcomes did not differ significantly.

Discussion: Kūmara consumption may reduce nocturnal wakefulness in infants, but further research incorporating objective sleep measures and exploring underlying mechanisms is needed.

Trial registration: Australian New Zealand Clinical Trials Registry identifier: ACTRN 12620000026921.

KEYWORDS
Complementary feeding; infant sleep; parental sleep; prebiotic food; sleep problem; wakefulness

Introduction

Sleep is an essential component of healthy growth and development in infants [1–3]. The quantity and quality of infant sleep play a pivotal role in cognitive development as well as emotional and physical health [1,2]. Infant sleep problems have been associated with an increased risk of childhood obesity, emotional dysregulation, and may also have implications on immune health [4–6]. Beyond its impact on infant health, their sleep also has a significant effect on family dynamics, caregiver wellbeing, and parenting competency [7,8]. Caregivers often view sleep in infants as problematic [3], with between 33% to 50% of parents reporting issues with their child's sleep behavior and poor sleep quality such as frequent night wakings and short sleep periods [9–11]. These concerns are among the most common reasons parents seek advice from health professionals [7,12]. Maternal

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Supplemental data for this article can be accessed online at https://doi.org/10.1080/1028415X.2026.2635535.

perception of infant sleep problems is strongly correlated with maternal mental health [10]. Caregivers who are mothers often experience fragmented sleep influenced by their infant's sleep patterns, leading to fatigue, and in severe cases, depressive symptoms [10,13]. Caregiver-reported infant sleep, therefore, is an important aspect in determining parental views on sleep and how it could influence their own sleep patterns [7,14]. This relationship is bidirectional, as parenting challenges and stress can further contribute to infant sleep issues [15].

During the first year of life, infant sleep undergoes rapid and significant changes, transitioning from fragmented sleep-wake cycles to more consolidated nocturnal sleep [16]. These changes are influenced by a range of factors, including developmental maturation [16], environmental conditions [14], and dietary practices [17]. The introduction of complementary food also marks a pivotal moment in infant's first year of life [18], where the foods introduced could affect infant sleep outcomes. Prebiotic foods have been shown to positively influence gut microbiota composition through microbial fermentation [19], enhancing the production of short-chain fatty acids (SCFAs), that could have a role in sleep regulation via the gut-brain axis [20,21], SCFAs play a role in hepatic gluconeogenesis, and are involved in secretion of hormones such as peptides YY (PYY), glucagon-like peptide-1 (GLP1) and leptin, which regulate appetite and promote satiety, potentially reducing night wakefulness and keeping infants asleep for a longer period of time [20]. Additionally, SCFAs and gut microbiota have been shown to influence serotonin production [21], a key precursor to melatonin, the hormone regulating sleep-wake cycles [22]. Given the potential mechanisms, prebiotic foods introduced during the complementary feeding period may have the potential to improve infant sleep and, in turn, caregiver sleep quality. However, there is no research examining the influence of introduction to prebiotic foods during complementary feeding on infant sleep patterns and dimensions of caregiver sleep that influence perceptions of their sleep quality, namely overnight sleep disturbance and sleep-related Impairment influencing daytime functioning.

Kūmara, a New Zealand-grown sweet potato, is a common and acceptable first food for infants [23], and has been recognized for its prebiotic effect [24]. Kūmara naturally contains resistant starch, a type of prebiotic that can be fermented and utilized by infant's gut microbiota [25]. A secondary outcome of the Seeding throUgh feediNg (SUN) randomized controlled trial [26] was designed to address this gap in knowledge by examining the effects of kūmara (K) and kūmara supplemented with resistant starch (K^+) extracted from green banana on infant sleep during the early complementary feeding phase (around 6 months of age to 10 months of age). This paper aimed to evaluate the effect of daily consumption of the intervention foods on caregiver-reported infant sleep patterns and caregivers' sleep quality. Based on the existing literature, the study hypothesized that infants in both the K and K^+ groups would have better and less problematic sleep, and therefore better caregiver sleep quality as compared to the control group. Furthermore, the K^+ group, which has added resistant starch, was expected to have the most pronounced benefits, including enhanced sleep duration and fewer sleep problems when compared to the other groups.

Methods

Participants

The SUN trial was a three-arm, parallel randomized controlled trial conducted at The University of Auckland Clinical Research Centre, New Zealand. Healthy infants residing in Auckland were eligible if they were 3–6 months of age, born at ≥32 weeks of gestation, weighed >2.5 kg at birth, were immunized according to the New Zealand Immunization Schedule [27], had not yet been introduced to solids, and were expected to begin solids around 6 months of age (but not before 4 months) [28]. Full details of the study protocol, including the inclusion and exclusion criteria, have been published [26], and only essential details are summarized here. The study commenced in February 2022 and concluded in June 2024. Ethical approval was obtained from the Northern A Health and Disability Ethics Committees (Ministry of Health, New Zealand; reference 20/NTA/9). The trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12620000026921). Digital or paper informed consent forms were obtained from primary caregivers, including parents and grandparents, for their participation and on behalf of infants prior to the collection of any biological samples. Participants were recruited through social media platforms (Facebook, Instagram), media releases, targeted events such as baby shows, and Plunket, New Zealand's largest provider of children and family support services. Study materials were also promoted in General Practitioner practices, childcare centers, shopping malls, universities, and postnatal and community groups.

A total of 281 eligible infants were randomized in the study and stratified by sex, as shown in Figure 1. The number of participants included in the analysis at CF2 and CF4, as well as those excluded due to withdrawal, loss to follow-up, missing Patient-Reported Outcomes Measurement Information System (PROMIS®) Sleep-Related Impairment or Sleep Disturbance data, or incomplete Brief Infant Sleep Questionnaire (BISQ) information, are also presented in Figure 1.

Intervention

Participants were randomized into one of three groups: control (n = 95), K (n = 93), or K$^+$ (n = 93) (Figure 1). Control group infants received no intervention (i.e., were introduced to solids according to the New Zealand Dietary Guidelines [28]), while the K and K$^+$ groups received either standard freeze dried kūmara powder (K) or kūmara powder with added resistant starch (K$^+$), respectively, alongside introduction to solids according to the New Zealand Dietary Guidelines [28]. Randomization was conducted using a 'participant randomization form' designed for the study on REDCap (Research Electronic Data Capture) hosted at the University of Auckland. Participants were allocated to study groups by an independent administrator, using a randomization list prepared by the trial statistician and concealed until the point of allocation. The two groups with kūmara intervention remained double-blinded throughout the trial. Intervention products were provided in identical 5 g sachets and consumed daily for four months, starting from the introduction of solids (approximately 6 months of age) until infants reached approximately 10 months of age. Adherence was tracked using a daily consumption log completed prospectively by caregivers, along with information collected through a monthly questionnaire on the average daily amount consumed in the past month. Any unused kūmara powder was returned to the research team and recorded at the participant's two-monthly clinic visit. Adherence to the protocol was defined as the daily consumption of 5 g of the intervention food on at least 80% of the monitored days within the previous month [26]. No additional dietary advice was provided to caregivers during the study period.

Outcome assessment

Demographic data were collected at baseline using mother (caregivers who were not the child's mother did not complete the questionnaire, $n = 3$) and child questionnaires, which included infant ethnicity, gestational age, mode of delivery, and caregiver education. Infants and parents sleep information were collected at three timepoints: Baseline (4–6 months of age, prior to the introduction of solids), Complementary Feeding Month 2 (CF2; two months post-randomization, approximately 8 months old), and Complementary Feeding Month 4 (CF4; four months post-randomization, approximately 10 months old). At each timepoint, infant sleep was assessed using the BISQ [29], and caregiver sleep quality was assessed using the 8-item short forms PROMIS® v1.0 Sleep-Related Impairment and PROMIS® v1.0 Sleep Disturbance [30].

Brief infant sleep questionnaire (BISQ)

The BISQ is a validated tool widely used in research to assess sleep patterns and behaviors in infants and toddlers [29,31]. It captures data on sleep-wake rhythms, sleep-related behaviors, sleeping arrangements, and bedtime routines over the past two weeks [29]. Total 24 h sleep duration was derived from the addition of nocturnal sleep and daytime sleep questions [29]. Problematic sleep was defined using dichotomous outcomes based on the variables collected from the BISQ questionnaire. Only the BISQ variables related to sleep-wake rhythms and caregiver-perceived problematic sleep were examined in this paper.

Infants were classified as having problematic sleep if they had <9 h of total sleep duration, >3 night awakenings, >1 h nocturnal wakefulness [29], or a settling time >30 min [9]. Caregiver perceptions of problematic sleep were captured by the question, 'Do you consider your child's sleep a problem?' with responses categorized as 'yes' for 'a very serious problem' or 'a small problem', and 'no' for 'not a problem at all' [32]

Patient-reported outcomes measurement information system (PROMIS®) sleep disturbance 8a and sleep-related impairment 8a

Caregiver sleep quality was assessed using the Sleep Disturbance 8a [30] and Sleep-Related Impairment 8a [30]. These questionnaires consist of eight items rated on a 5-point scale, measuring the frequency of

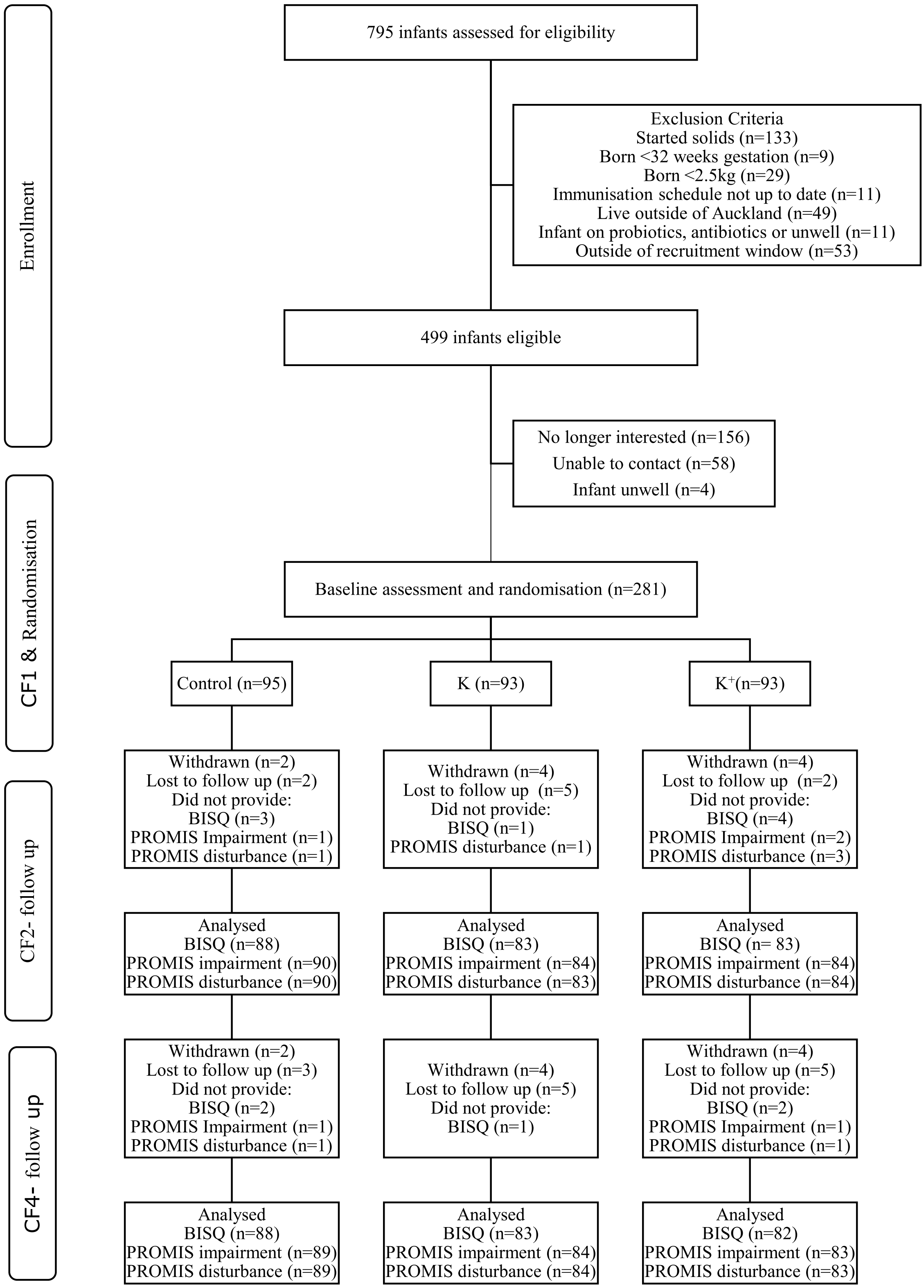

Figure 1. CONSORT flow chart of SUN participants.

CF2; Complementary Feeding Month 2. CF4; Complementary Feeding Month 4. BISQ; Brief Infant Sleep Questionnaire. PROMIS® Disturbance; PROMIS® Short Form v1.0 – Sleep Disturbance 8a. PROMIS® Impairment; PROMIS® Short Form v1.0 – Sleep-Related Impairment 8a.

problems related to sleep impairment and Sleep Disturbance over the past week [30]. Raw total scores were converted to standardized T-scores using the HealthMeasures Scoring Service (www.assessmentcenter.net/ac_scoringservice). The T-scores are based on a normative adult reference population in the United States. Scores above 55 for Sleep Disturbance and 54 for Sleep-Related Impairment indicate the presence of symptoms, with increasing scores indicating greater severity [30,33]. Internal consistency was assessed using Cronbach's alpha. The Sleep Disturbance and Sleep-Related Impairment scales demonstrated high internal consistency of Cronbach's α of 0.87 and Cronbach's α of 0.89, respectively. The 'Disturbed' and 'Impaired Sleep' of caregivers were defined using dichotomous outcomes based on T-scores. Sleep Disturbance was dichotomized into mild-to-severe disturbance (T-score >55) and within normal limits (T-score ≤55). Similarly, Sleep-Related Impairment was categorized as mild-to-severe impairment (T-score >54) and within normal limits (T-score ≤54) [33].

Data analysis

The main trial was powered to detect differences in the primary outcome (detailed in the protocol paper) [26]. No additional sample size calculations were performed for secondary outcomes, as these were considered exploratory and dependent on the sample size determined for the primary outcome. This paper examined the effects of kūmara (K) and kūmara with added resistant starch (K+) on infant sleep patterns and caregiver sleep quality at CF2 and CF4, compared with a control group. Statistical analyses were conducted using IBM SPSS Statistics (version 28.0; IBM Corp., Armonk, NY, USA). A two-sided *p*-value of <0.05 was considered statistically significant. Researchers were blinded to group allocation during data processing and analysis.

Means, standard deviations (SDs), and proportions were used to describe participants' baseline characteristics as well as infant and caregiver sleep measures at CF2 and CF4. Adjusted regression analyses were performed to assess the effects of the intervention foods on infant and caregiver sleep variables at CF2 and CF4, using the control group as the reference. All models were adjusted for sex (the stratification factor), the corresponding baseline values of each outcome variable, and the age of introduction to solids at baseline. Since the four-month intervention began at the introduction to solids, the variable was included in the model to account for the variations in age at which the infant started solids. Multiple linear regression was used for continuous sleep variables, with results presented as beta coefficients (mean differences) and 95% confidence intervals (95% CI). For dichotomous sleep variables, multiple logistic regression was used, with results reported as odds ratios (OR) and 95% CI.

Additional exploratory analyses were conducted to compare infants' and caregivers' sleep measures between K and K + groups at CF2 and CF4.

Results

Table 1 presents the baseline characteristics, including infant baseline sleep measures (BISQ) and caregiver sleep quality (PROMIS® questionnaires) of participants who completed the BISQ at baseline.

Participants' characteristics were similar across the control and both intervention groups at baseline, reflecting the randomization process. No major imbalances were observed between the groups. Approximately 64% of the infants were European, while 11% were Māori, 2% were Pacific, 19% were Asian, and 3% were MELAA (Middle Eastern/Latin American/African) and/or Other ethnicity. The majority of infants (>95%) were born full term (>37 weeks), delivered vaginally (>60%), and exclusively breastfed at baseline (>60%). The mean (SD) age of introduction to solids was 5.3 (0.6) months. Around 60% of infants started solids at 5 months of age and 34% started at 6 months of age. Additionally, over 90% of the caregivers had completed tertiary and higher education. A small proportion of the caregivers reported Sleep Disturbance (28.3%) while around half experienced impaired sleep (52.4%). Infants in this cohort slept an average of 10.5 h during nighttime, and napped for 3.4 h during the day, adding up to 13.8 h of total sleep duration. No infant slept less than 9 h in a 24-hour period. The majority of the infants had no caregiver-reported sleep problems, 81.9% had three or fewer night wakings, 81.2% were awake for one hour or less during the night, and 83.8% took 30 min or less to settle to sleep at night. However, around one third (38.4%) of the parents viewed their infant sleep as problematic.

Table 1. Baseline characteristics of SUN participants that completed BISQ at baseline.

	All (n = 271)		Control (n = 95)		K⁺ (n = 88)		K (n = 88)	
	n		n		n		n	
Age of infants at baseline (months)								
Mean (SD)	271	4.9 (0.5)	95	4.9 (0.5)	88	4.9 (0.5)	88	5.0 (0.4)
Infant's sex								
Female	134	49.5	47	49.5	44	50.0	43	48.9
Male	137	50.6	48	50.5	44	50.0	45	51.1
Infant ethnicity[a]								
European	173	64.1	57	60.0	58	66.7	58	65.2
Māori	30	11.1	10	10.5	9	10.3	11	12.5
Pacific	5	1.9	1	1.1	1	1.1	3	3.4
Asian	53	19.6	19	20.0	18	20.7	16	18.2
MELAA + Others	9	3.3	8	8.4	1	1.1	0.0	0.0
Missing	*1*				*1*			
Infant gestational age (weeks)								
≥37	262	96.7	91	95.8	87	98.9	84	95.5
<37	9	3.3	4	4.2	1	1.1	4	4.5
Mode of delivery								
Vaginal	176	64.9	61	64.2	58	65.9	57	64.8
Caesarean[b]	95	35.1	34	35.8	30	34.1	31	35.2
Mode of milk feeding[c]								
Exclusive breastfeeding[d]	157	66.2	52	62.7	47	61.0	58	75.3
Full breastfeeding[e]	19	8.0	8	9.6	5	6.5	6	7.8
Partial breastfeeding[f]	60	25.3	23	27.7	24	31.2	13	16.9
Formula feeding[g]	1	0.4	0	0.0	1	1.3	0	0.0
Missing	34		*12*		*11*		*11*	
Age of introduction to solids (months)								
Mean (SD)	268	5.3 (0.6)	94	5.3 (0.6)	87	5.3 (0.6)	87	5.4 (0.5)
4 months	11	4.1	7	7.4	3	3.4	1	1.1
5 months	164	61.0	56	59.6	54	61.4	54	62.1
6 months	90	33.5	31	33.0	28	31.8	31	35.6
7 months	3	1.1	0	0.0	2	2.3	1	1.1
Missing	*3*		*1*		*1*		*1*	
Caregiver education level								
Secondary school or lower	14	5.2	6	6.3	5	5.7	3	3.4
Tertiary/university	257	94.8	89	93.7	83	94.3	85	96.6
PROMIS® questionnaire								
Sleep Disturbance T-score								
Mean (SD)	269	51.6 (6.7)	94	51.3 (6.7)	88	51.3 (7.2)	87	52.4 (6.3)
Normal	193	71.7	68	72.3	65	73.9	60	69.0
Mild to Severe	76	28.3	26	27.7	23	26.1	27	31.0
Missing	*2*		*1*				*1*	
Sleep-Related Impairment T-score								
Mean (SD)	269	55.5 (7.6)	95	55.1 (7.5)	87	54.8 (8.3)	87	56.8 (7.0)
Normal	128	47.6	52	54.7	42	48.3	34	39.1
Mild to Severe	141	52.4	43	45.3	45	51.7	53	60.9
Missing	*2*				*1*		*1*	
BISQ								
Nocturnal sleep duration, h								
Mean (SD)	271	10.5 (1.1)	95	10.5 (1.1)	88	10.5 (1.2)	88	10.5 (1.1)
Daytime sleep duration, h								
Mean (SD)	271	3.4 (1.0)	95	3.3 (0.9)	88	3.4 (1.0)	88	3.4 (1.2)
Total sleep duration, h								
Mean (SD)	271	13.8 (1.5)	95	13.7 (1.5)	88	13.9 (1.5)	88	13.8 (1.4)
≥9 h	271	100	95	100	88	100	88	100
<9 h	0	0	0	0	0	0	0	0
Night wakings, no.								
Mean (SD)	271	2.3 (1.5)	95	2.4 (1.6)	88	2.1 (1.2)	88	2.3 (1.6)
≤3 wakings	222	81.9	77	81.1	74	84.1	71	80.7
>3 wakings	49	18.1	18	18.9	14	15.9	17	19.3
Nocturnal wakefulness, min								
Mean (SD)	271	47.5 (39.9)	95	48.9 (43.7)	88	49.2 (0.7)	88	44.4 (34.7)
≤ 1 h	220	81.2	77	81.1	72	81.8	71	80.7
> 1 h	51	18.8	18	18.9	16	18.2	17	19.3
Settling time, min								
Mean (SD)	271	24.1 (19.4)	95	23.6 (20.4)	88	26.1 (20.6)	88	22.7 (17.1)
≤30 min	227	83.8	81	85.3	71	80.7	75	85.2
> 30 min	44	16.2	14	14.7	17	19.3	13	14.8
Problematic sleep								
No	167	61.6	55	57.9	60	68.2	52	59.1
Yes	104	38.4	40	42.1	28	31.8	36	40.9

Data are presented as number (n); mean (Standard Deviation); percentage. [a]Infant ethnicity was prioritized using the Statistics NZ classification Level 1: Māori, Pacific Peoples, Asian, MELAA, Other, and European [3,6,20,21,23,34]; MELAA and Other were combined for analysis purposes. [b]Ceasarean includes planned and emergency. [c]Mode of milk feeding status at baseline. [d]Exclusive breastfeeding: Only breastmilk from the breast or expressed breastmilk and prescribed medicines have been given from birth. [e]Full breastfeeding: breastmilk only with other liquids except a minimal amount of water or prescribed medicines in the past 48 h. [f]Partial breastfeeding: Mixture of breastmilk and infant formula. [g]Formula feeding: Infant formula only. BISQ; Brief Infant Sleep Questionnaire, MELAA + Others; Middle Eastern/Latin American/African + Other ethnicity, PROMIS®; Patient-Reported Outcomes Measurement Information System.

The baseline characteristics of all participants who participated in the SUN trial, as well as those with completed the BISQ at CF2 and CF4 are presented in **Appendix A.** At least 90% of the total participants completed the BISQ at both CF2 and CF4, and no difference in baseline characteristics were found between these groups and the overall study population. The mean intervention adherence among infants who completed the BISQ at CF2 and CF4 were similar between groups, with more than 80% adherence observed for both the K and K^+ groups. Among infants whose caregivers completed the BISQ at CF2 and CF4, fewer infants in the K group adhered to the protocol (68.3%) compared to the K^+ group (78.5%) (data only reported in text). Most BISQ responses were provided by mothers (98.4%; n = 250) at CF2 and (98.4%; n = 249) at CF4. Only three fathers (1.2%) and one grandparent (0.4%) completed the BISQ at CF2 and CF4, respectively (data only reported in text).

Table 2 compares the Control group with the K and K^+ groups for caregiver sleep quality (PROMIS® questionnaires) and infant sleep variables (BISQ) at CF2 and CF4. A significant mean difference was observed in nocturnal wakefulness at CF4, where infants in the K group were awake 8.4 min (on average) less per night compared to the control group (β = −8.4, 95% CI: −15.66 to −1.20, $p = 0.023$) (Table 2). At CF2, infant daytime sleep duration in the K^+ group was 11.4 min longer (β = 0.19, 95% CI: −0.00–0.39, $p = 0.053$) than the control group, suggesting a trend close to statistical significance. No significant differences were found between groups for caregiver Sleep Disturbance T-scores, Sleep-Related Impairment T-scores, or other infant sleep measures.

Table 3 presents odds ratios comparing the odds of proportions of caregivers and infants with problematic sleep between the K or K^+ group and the control group. In this study cohort, no infants had a total sleep duration of <9 h; hence, this outcome measure was not included in Table 3. Infants in the K^+ group were more likely to wake more than three times a night (OR = 2.99, 95% CI: 0.95–9.45, $p = 0.061$) compared to the control group at CF2. Caregivers in the K^+ group were also more likely to perceive their infant's sleep as problematic (OR = 2.13, 95% CI: 1.00–4.54, $p = 0.051$) at CF2. Conversely, infants

Table 2. Comparison of adjusted mean differences in caregiver sleep quality scores (PROMIS® questionnaires) and caregiver-reported infant sleep variables (BISQ) between K^+ vs Control and K vs Control at CF2 and CF4.

	Control[1]	K^{+a}	Mean difference[b] (95% CI) K^+ *vs* Control	*p*-value	K^a	Mean difference[b] (95% CI) K *vs* Control	*p*-value
Caregiver							
Sleep Disturbance, T-score							
CF2	51.1 ± 5.6	51.3 ± 6.9	0.45 (−1.17; 2.06)	0.584	51.9 ± 5.5	0.43 (−0.97; 1.83)	0.546
CF4	50.8 ± 6.4	50.6 ± 7.3	0.12 (−1.75; 2.00)	0.896	49.9 ± 6.6	−1.10 (−2.86; 0.76)	0.252
Sleep-Related Impairment, T-score							
CF2	54.4 ± 7.5	53.6 ± 8.2	−0.56 (−2.47; 1.35)	0.563	54.9 ± 7.1	0.27 (−1.51; 2.04)	0.767
CF4	53.7 ± 7.0	53.8 ± 8.4	0.07 (−1.83; 1.98)	0.939	54.3 ± 8.3	−0.01 (−2.04; 2.03)	0.995
Infant							
Nocturnal sleep duration, h							
CF2	10.7 ± 0.9	10.5 ± 1.0	−0.18 (−0.41; 0.06)	0.134	10.8 ± 0.9	0.04 (−0.01; 0.29)	0.749
CF4	10.7 ± 1.0	10.6 ± 1.0	−0.10 (−0.36; 0.16)	0.458	10.8 ± 1.0	0.05 (−0.22; 0.32)	0.724
Daytime sleep duration, h							
CF2	2.6 ± 0.7	2.9 ± 0.6	0.19 (−0.00; 0.39)	0.053	2.7 ± 0.8	0.01 (−0.19; 0.21)	0.918
CF4	2.4 ± 0.6	2.5 ± 0.7	0.15 (−0.04; 0.34)	0.119	2.4 ± 0.7	0.01 (−0.18; 0.20)	0.921
Total sleep duration, h							
CF2	13.4 ± 1.1	13.4 ± 1.3	−0.01 (−0.31; 0.30)	0.967	13.5 ± 1.0	0.07 (−0.21; 0.35)	0.627
CF4	13.1 ± 1.1	13.2 ± 1.1	−0.02 (−0.34; 0.31)	0.914	13.2 ± 1.1	0.07 (−0.25; 0.39)	0.650
Night wakings, no.							
CF2	2.5 ± 1.6	2.1 ± 1.4	−0.32 (−0.75; 0.11)	0.139	2.4 ± 1.8	0.02 (−0.43; 0.46)	0.946
CF4	2.2 ± 1.6	2.1 ± 1.5	0.03 (−0.41; 0.47)	0.893	2.3 ± 1.7	0.16 (−0.30; 0.61)	0.497
Nocturnal wakefulness, min							
CF2	38.5 ± 28.7	31.4 ± 31.9	−6.66 (−14.76; 12.00)	0.095	35.6 ± 28.3	−0.12 (−8.10; 7.86)	0.973
CF4	34.1 ± 29.5	27.3 ± 25.0	−5.64 (−13.26; 1.98)	0.146	**24.7 ± 20.8**	**−8.40 (−15.66; −1.20)**	**0.023**
Settling time, min							
CF2	20.7 ± 16.4	18.9 ± 14.1	−2.04 (−6.12; 2.04)	0.327	19.5 ± 18.3	−1.14 (−5.82; 3.54)	0.637
CF4	19.9 ± 17.6	18.4 ± 14.5	−9.60 (−5.58; 3.66)	0.680	17.6 ± 11.3	−1.50 (−5.82; 2.76)	0.482

95%CI: 95% confidence interval; CF2: Complementary Feeding month 2; CF4: Complementary Feeding month 4. [a]Values are represented as mean ± standard deviation (SD). bPairwise comparisons were conducted using multiple linear regression models with the control group as reference. Analyses were adjusted for sex, age at introduction of solids, and corresponding sleep variable measured at baseline. Bold text indicates statistically significant differences ($p < 0.05$). BISQ; Brief Infant Sleep Questionnaire, PROMIS®; Patient-Reported Outcomes Measurement Information System.

Table 3. Comparison of adjusted odds ratios for caregiver sleep problems (PROMIS® questionnaires) and infant problematic sleep[1a] (BISQ) between K$^+$ vs Control and K vs Control at CF2 and CF4.

	Control[b]	K^{+b}	Odds ratio (95%CI)[c] K$^+$ *vs* Control	*p*-value	K[b]	Odds ratio (95%CI)[c] K *vs* Control	*p*-value
Caregiver							
Sleep Disturbance, T-score							
CF2	18 (20)	21 (25.0)	1.36 (0.62; 2.97)	0.444	23 (27.7)	1.57 (0.72; 3.41)	0.256
CF4	17 (19.1)	21 (25.0)	1.54 (0.70; 3.40)	0.285	12 (14.3)	0.70 (0.30; 1.64)	0.416
Sleep-Related Impairment, T-score							
CF2	42 (46.7)	37 (44.0)	0.76 (0.38; 1.53)	0.435	47 (56.0)	1.34 (0.68; 2.67)	0.402
CF4	40 (44.9)	38 (45.2)	0.85 (0.43; 1.69)	0.638	41 (48.8)	0.90 (0.46; 1.76)	0.757
Infant							
Night wakings (>3 wakings)							
CF2	19 (21.6)	16 (19.3)	0.87 (0.39;1.95)	0.733	22 (26.5)	1.34 (0.61; 2.95)	0.472
CF4	15 (17)	15 (18.3)	1.41 (0.56; 3.53)	0.466	18 (21.7)	1.55 (0.64; 3.71)	0.329
Nocturnal wakefulness (>1 h)							
CF2	7 (8.0)	12 (14.5)	2.99 (0.95; 9.43)	0.061	9 (10.8)	1.63 (0.53; 5.01)	0.399
CF4	8 (9.1)	5 (6.1)	0.66 (0.19; 2.26)	0.503	2 (2.4)	0.22 (0.04; 1.10)	0.066
Settling time (>30 min)							
CF2	9 (10.2)	5 (6.0)	0.49(0.14; 1.76)	0.274	10 (12.0)	1.24 (0.44; 3.46)	0.683
CF4	10 (11.4)	6 (7.3)	0.56 (0.15; 2.12)	0.396	4 (4.8)	0.40 (0.11; 1.47)	0.166
Problematic sleep (Yes)							
CF2	36 (40.9)	40 (48.2)	2.13 (1.00; 4.54)	0.051	42 (50.6)	1.75 (0.88; 3.47)	0.112
CF4	39 (44.3)	39 (47.6)	1.37 (0.69; 2.70)	0.366	39 (47.0)	1.22 (0.64; 2.33)	0.544

95%CI: 95% confidence interval; CF2: Complementary Feeding month 2; CF4: Complementary Feeding month 4. [a]Total sleep duration measured by BISQ <9 h (n = 0), excluded from the table. [b]Values are represented as n (%).[c]Pairwise comparisons were conducted using adjusted binary logistic regression models with the control group as reference. Analyses were adjusted for sex, age at introduction of solids, and corresponding sleep variable measured at baseline. BISQ; Brief Infant Sleep Questionnaire, PROMIS®; Patient-Reported Outcomes Measurement Information System.

in the K group at CF4 were less likely to wake for more than an hour at night (OR = 0.22, 95% CI: 0.04–1.10, $p = 0.066$), compared to the control group. No significant differences were observed between groups for caregivers with mild to moderate Sleep Disturbance or Sleep-Related Impairment at either timepoint.

Comparisons between the K and K$^+$ groups at CF2 and CF4 revealed no significant mean differences or odd ratios for any of the sleep outcome variables (Appendices B and C).

Discussion

To the best of our knowledge, this is the first randomized control trial to investigate the effects of prebiotic intervention foods – standard kūmara (K) and kūmara with added resistant starch extracted from green banana (K$^+$) – on caregiver-reported infant sleep and caregivers' sleep quality during the first four months of complementary feeding. This study hypothesized that both infants in the K and K$^+$ groups would have better and less problematic sleep leading to better caregiver sleep quality as compared to the control group, with K$^+$ expected to have the most pronounced effects due to its additional prebiotic properties. The baseline sleep measures are comparable to a study that assessed sleep using BISQ in a cohort of infants of similar age from Australia and New Zealand [9], as well as a recently published New Zealand study that used the BISQ- Revised [35]. Distribution of ethnicities of infants who completed BISQ questionnaire at baseline largely reflected the 2023 New Zealand census data [36], although Māori and Pacific populations were slightly underrepresented. Given that the trial was not designed to achieve a fully representative sample, caution is warranted when generalizing these findings both within New Zealand and internationally.

After four months of complementary feeding, infants in the K group woke on average 8.4 min less per night compared to the control group, as reported by caregivers. While this difference may appear small in isolation, it could represent a meaningful improvement, especially for sleep-deprived caregivers when accumulated across an entire week (58.8 min) [10]. No significant differences in the frequency of night wakings were observed, suggesting that the positive effect for infants in the K group might be due to shorter durations of wakefulness rather than fewer night wakings. This aligns with the findings of a non-significant trend in which infants in the K group had lower odds of staying awake for more than an hour at night (classified as problematic sleep) compared to controls ($p = 0.066$). This highlights a potential benefit of kūmara in facilitating infants to return to sleep swiftly, possibly preventing the development of a sleep problem [37]. In this study, kūmara, identified as a prebiotic food [24], was blanched and cooled twice to increase its resistant starch (resistant starch class 3) content [38], which may have enhanced the infant's gut health and promoted satiety [39], reducing the need for prolonged nighttime feedings and allowing infants to go back to sleep quicker. However, further investigation is required to confirm this proposed mechanism. Examination of infant gut microbiota composition and SCFA production could provide insight into the effects of prebiotic food on sleep regulation [20,21].

In the K^+ group, a trend of infants sleeping 11.4 min longer during the daytime ($p = 0.053$) compared to the control group was observed at CF2 (around 8 months of age). Although not statistically significant, this may hold clinical importance, as caregivers often consider daytime naps essential for an infant's overall functioning, including potential cognitive benefits (1), and for supporting caregivers' daily routines (2). This increase in daytime sleep, however, did not translate to lower odds of caregiver-reported problematic sleep. In fact, infants in the K^+ group were reported to have higher odds of staying awake for more than an hour at night ($p = 0.061$) and having problematic sleep ($p = 0.051$) compared to the control group at CF2. One possible explanation is that longer daytime naps could result in shorter night time sleep periods, [40] which in this study may have contributed to infants staying awake for more than an hour at night. Prolonged nighttime wakefulness is a common cause of caregiver perceived infant sleep problem [41], and therefore leading to higher parental reported problematic sleep in this study cohort. Another potential explanation for this relationship is the variability in infants' tolerance to resistant starch, in which infants in K^+ group received a higher dose of resistant starch through the intervention food compared to the K group. While gastrointestinal discomfort associated with resistant starch intake has been observed in adults [42], there is a paucity of studies examining feeding interventions involving resistant starch in infancy. In addition, dietary guidelines on total fiber intake, of which resistant starch is categorized as a fraction [43], are lacking in infants under 12 months of age [44,45]. Although an in-vitro study examining the fermentation capacity of healthy infants' fecal samples has demonstrated their ability to ferment resistant starch [25], existing human research has primarily focused on its beneficial effects in managing watery stools or diarrhea [46], leaving its gastrointestinal impact on otherwise healthy infants largely unexplored. This warrants future research that incorporates direct measures of gastrointestinal symptoms or use of validated questionnaires to better understand these effects. In contrast with the hypothesis, the added prebiotic effect did not contribute to better and less problematic sleep in infants from K^+ group, suggesting a complex relationship between sleep and feeding at this age.

There were no significant differences or trends in caregiver sleep quality across groups, as assessed by the PROMIS® Sleep Disturbance and impairment scores. This is not unexpected since the SUN study did not specifically recruit participants who had infants with sleep issues [47], and minor changes in infant sleep might not drastically affect caregiver's perceptions of their sleep quality. It is possible that objective measures of caregiver sleep may be more sensitive in detecting subtle changes in their sleep-wake patterns associated with infant sleep [48].

Strength and limitations

Strengths of the study include the high average adherence rate to the kūmara intervention (>80%) and a moderately good adherence to protocol (>68%), along with a high completion rate for the BISQ (>90%) at CF2 and CF4, despite these questionnaires being secondary outcomes of the main trial. Additionally, the baseline characteristics of infants whose caregivers completed the BISQ were similar to those of the overall SUN cohort, minimizing selection bias. Another strength of the study was the use of PROMIS® sleep questionnaires, which provides a comprehensive assessment of caregiver sleep by evaluating nighttime sleep disturbance, and daytime functioning using the Sleep-Related Impairment questionnaire [30].

Several limitations should be considered when interpreting these findings. Firstly, the BISQ is a subjective assessment tool and is therefore susceptible to reporting and recall biases [3]. It is less accurate at capturing the duration of sleep as compared to an objective assessment tool such as actigraphy [49]. The BISQ is typically used in larger cohort studies that have recruited more participants (i.e. >500) [9,50], which may partly account for the trends observed in this study not achieving statistical significance. Additionally, as this is an exploratory investigation and a secondary outcome of the SUN study, the sample size was not powered to detect significant changes in sleep measures. Furthermore, participants were not recruited based on sleep problems, which limits the findings related to problematic sleep and explains the absence of infants with less than 9 h of nocturnal sleep per night. Lastly, the caregivers were skewed towards highly educated (>90% completed tertiary and higher education) and mothers who were exclusively breastfeeding (>60%) at baseline, potentially limiting the generalizability of these findings to more diverse feeding methods.

Conclusions

To our knowledge, the study is the first randomized controlled trial to explore the effects of prebiotic intervention foods on caregiver-reported infant sleep and caregiver sleep quality during complementary feeding. The findings provide preliminary insights into the potential benefits of kūmara by reducing nocturnal wakefulness in infants after four months of daily consumption. However, while the kūmara enriched with resistant starch (K^+) showed a (non-significant) trend of increased daytime sleep duration at ten months of age, it was associated with trends toward more caregiver-reported sleep problems and extended nighttime wakefulness (>1 h). These findings are partially aligned with the study hypothesis, with infants in the K group demonstrating reduced nocturnal wakefulness at the end of the four-month intervention, whereas no such improvement was observed in the K^+ group infants. In addition, there was no significant difference in caregiver sleep quality between groups at any timepoint.

Future studies should incorporate objective sleep measures such as actigraphy and explore gut microbiota diversity and short-chain fatty acid concentrations to better understand the mechanisms underlying the observed effects. Research specifically powered for infant sleep as a primary outcome are essential to confirm these findings and to inform evidence-based recommendations for complementary feeding practices that support both infant sleep and caregiver wellbeing.

Author contributions

XF: Conceptualization, Methodology, Software, Data curation, Investigation, Writing – original draft, Project administration; ALL, CRW, and BCG: Conceptualization, Methodology, Resources, Writing – review & editing, Supervision, Project administration; CRW: Funding acquisition; TC and YJ: Formal analysis, Writing – review & editing; RLL: Investigation, Project administration, Writing – review & editing; NM: Investigation, Writing – review & editing; BCG: Validation. All authors have read and approved the final article.

Disclosure statement

No potential conflict of interest was reported by the author(s).

Funding

This work was funded by New Zealand Ministry of Business Innovation and Employment as part of the High Value Nutrition – National Science Challenge.

Data availability statement

The authors confirm that the data supporting the findings of this study are available within the article and its supplementary materials.

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