

Supplement File 1_Additional Results

SUPPLEMENT FILE 1

Main Text Title- Adjunct Role of Potassium in Painful Rheumatoid Arthritis: A Randomized Controlled Study of Diet and Food Supplement based Intervention in Patients on Supervised Standard Care

SUBJECT: Additional Efficacy Results

Table 1: Median (Standard deviation, 95% confidence intervals) serum cortisol, serum and urine potassium over 16 weeks study period: A randomized controlled potassium-diet study in 172 patients of chronic rheumatoid arthritis on standard treatment[Arm A= potassium rich vegetarian diet, B= potassium rich vegetarian diet plus potassium food supplement, C=control routine diet]-per protocol analysis

Variable	Gp	Baseline	4 weeks	8 weeks	12 weeks	16 weeks	p*	P1	P2
Serum K (mEq/L)	A	3.9 (0.5)	3.8 (0.4)	3.9(0.5)	3.9(0.5))	3.6 (0.5)	0.21	0.59	0.36
	B	3.8(0.5)	3.8(0.4)	3.7 (0.4)	3.9 (0.5)	3.9 (0.4)	0.35		
	C	3.9 (0.5)	3.7 (0.4)	3.7 (0.5)	4 (0.5)	3.8(0.5)	0.99		
Serum Na (mEq/l)	A	140 (6.6)	139 (5.1)	141.5 (5)	142 (6.7)	139 (9.3)	0.52	0.67	0.41
	B	140(5.4)	137 (4.7)	141.5 (9.8)	142 (7.2)	139 (9.1)	0.40		
	C	142 (6.1)	139 (4.3)	139 (6.1)	143 (8.9)	140 (8.1)	0.49		
Urine K (mEq/l)	A	37.6 (25.9)	39 (39.1)	51.5(32.3)	65(42.1)	65.5(34.7)	0.01	0.77	0.50
	B	40 (26.1)	43 (29.6)	48 (34.1)	45 (23.6)	59 (38.5)	0.02		
	C	34.8 (28.9)	45 (39.8)	45 (30.4)	47 (27.8)	55 (36.6)	0.00		
Urine Na (mEq/l)	A	105.5(79.2)	81 (59.2)	95.5 (45.2)	65(93.3)	117 (44.7)	0.51	0.81	0.82
	B	97(63.4)	94.5(84.4)	98.5(70.8)	81(55.3)	116 (53.8)	0.61		

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	C	99(87.4)	104(66.6)	100(58.5)	101(55.4)	105(43.9)	0.53		
Serum Cortisol (µg/dl) (8-1030 am)	A	5.7 (4.2)	6.8 (3.9)	7.6 (7.1)	8.4 (8.9)	8.2 (7.8)	0.00	0.59	0.55
	B	5.5 (4.8)	6.5 (5.7)	6.9(6.6)	9.4 (9)	8.9(8.5)	0.00		
	C	5.4 (4)	7.6 (7.6)	6.3 (6.6)	8.1 (7.6)	7.1 (7)	0.01		
<p>Note: K: potassium; Na: sodium; Gp: group; Number of patients: 52 Arm A, 50 Arm B & 53 Arm C; Number of Serum samples: 100% serum samples at baseline and completion and 90-94% other visits; Number of Spot Urine Potassium samples: least 48 available at each visit; Urine sample collected for spot urine K assay between 8-11 am; Blood collected for serum cortisol between 8-1030 am; Significant p<0.05two-tailedd (ANOVA); No significant differences at p<0.05 between groups at study visits using ANOVA ;p*: in-between group change: p1:baseline comparison ; p2: study completion (week 16) comparison; See main text for details</p>									

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Table 2: Correlations (r) between potassium (K) related diet and laboratory variables at baseline and completion and with selected outcomes in patients with symptomatic rheumatoid arthritis (RA) randomized (n=172 patients) to a diet intervention drug trial; data pertains to 155 patient completers.

Variable	Diet K (B)	Diet K (C)	Serum K (B)	Serum K (C)	Urine K (B)	Urine K (C)
Diet K (B)	1	0.038	-0.345**	-0.127	-0.056	0.085
Diet K (C)	0.038	1	-0.129	0.021	0.002	-0.089
Serum K (B)	-0.345**	-0.129	1	0.304**	0.086	-0.09
Serum K (C)	-0.127	0.021	0.304**	1	0.03	-0.94
Urine K (B)	-0.056	0.002	0.086	0.03	1	0.051
Urine K (C)	0.085	-0.089	-0.09	-0.94	0.051	1
Pain VAS (C)	-0.009	-0.193*	-0.081	-0.068	0.114	0.115
Pain MCID (C)	0.114	-0.191*	-0.071	-0.105	0.094	0.088
DAS 28 (C)	0.018	0.006	-0.041	0.029	-0.008	0.079

Note: n:number; B:baseline; C:completion; Diet: daily estimation based on 'Food Composition Table (India); Urine K: spot morning urine assay; Pain VAS: pain visual analogue scale; MCID: minimum clinically important difference; DAS 28: disease activity score based on 28 joints; *:p<0.05; **:p<0.01; See methods above and main test for further explanation

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Table 3: Efficacy variables of patients suffering from RA on standard of care treatment in intervention and control group (A; K rich diet , B; K rich diet + dietary K suppl C; routine diet): showing mean change (95% confidence interval) over study period (16 weeks) - an Intention to treat analysis.

Variable	A(n=57)		B(n=58)		C(n=57)		P* ANOVA
	Baseline	Mean change	Baseline	Mean change	Baseline	Mean change	
Pain VAS (0-100mm)	5.42	-1.31 (-1.93,-0.7)	5.41	-1.98 (-2.62,-1.34)	5.26	-1.24 (-1.8,-0.67)	0.17
JCSW (range 0-66)	2.37	-1.82 (-2.37,-1.27)	2.49	-0.69 (-1.88,0.48)	2.44	-1.60 (-2.61,-0.6)	0.2
JCPT (range 0-68)	11.19	-9.23 (-11.82,-6.64)	13.11	-8.58 (-12.11,-5.05)	11.64	-5.78 (-9.38-2.19)	0.27
Patient Assess (Grade 1-5)	1.35	-0.42 (-0.58,-0.27)	1.35	-0.41 (-0.63,-0.19)	1.41	-0.5 (-0.69,-0.3)	0.21
HAQ (range 0-24)	5.32	-1.89 (-2.85,-0.93)	5.11	-2.14 (-3.38,-0.91)	4.5	-0.72 (-1.73,0.27)	0.13
General Health (0-100 mm VAS)	51.03	13.44 (8.05,18.83)	51.49	13.41 (6.76,20.06)	50.91	10.30 (4.58,16.02)	0.68
SF36 Physical score	42.03	1.78 (-0.3, 3.87)	41.48	2.83 (0.40, 5.26)	43.28	0.31 (-1.38, 2.01)	0.23
SF36 Mental score	40.20	2.5673 (-0.01,5.15)	41.05	1.30 (-0.94, 3.55)	40.80	2.29 (-0.43, 5.02)	0.76
ESR mm fall 1 st hour	70.62	-8.38 (-15.62, -1.13)	69.03	-10.88 (-18.75, -3.02)	65.08	-9.29 (-15.95, -2.63)	0.88
CRP mg/dl	33.85	-22.02 (-35.16, -8.87)	26.61	-8.33 (-15.90, -0.75)	25.6	-11.74 (-23.55, 0.06)	0.2
DAS 28 ESR	4.91	-1.46 (-1.79, -1.14)	5.01	-1.18 (-1.60, -0.77)	4.83	-1.02 (-1.44, -0.60)	0.25

Note: n: number of patients; VAS: visual analogue scale; JCSW: swollen joint count; JCPT: painful joint count; HAQ: health assessment questionnaire (function); SF 36 : Short Form 36 (quality of life); ESR: erythrocyte sedimentation rate; CRP:C-Reactive protein; DAS: disease activity index; Higher value/scores at baseline except for general health and SF 36 indicate worst outcome; Normal ranges are shown in parenthesis after variable; See Text for details

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Table 4: Rheumatoid Arthritis Medication (number of patients) at randomization baseline (week 0) and study completion (week 16) in a randomized controlled three arm dietary potassium intervention study (n=172) in chronic Rheumatoid Arthritis [A= potassium rich diet; B=potassium rich diet plus potassium food supplement; C= control routine diet]

Arm/ Drug	A		B		C		p1*	p2*
Time points/week	0 (n=57)	16 (n=52)	0 (n=57)	16 (n=50)	0 (n=58)	16 (n=53)		
DMARD (Single or Combo) + Prednisolone/P (low dose steroid, 5 mg or less daily dose)								
DMARD (Single or combination) plus prednisolone-total	40	35	35	32	41	39	0.49	0.56
Methotrexate(P)	16	13	20	17	12	17	0.2	0.29
HCQS (P)	8	0	2	1	6	2	0.12	0.46
Sulfasalazine (P)	0	2	1	0	6	1	0.04	0.35
Methotrexate + HCQS (P)	3	8	6	8	5	6	0.46	0.84
Methotrexate + Sulfasalazine (P)	8	8	4	4	5	7	0.57	0.42
Sulfasalazine+ HCQS (P)	0	0	0	0	5	1	0.08	0.37
Methotrexate + Sulfasalazine+ HCQS (P)	5	4	2	2	2	5	0.34	0.35
DMARD Combination (no prednisolone)								
DMARD combination-total	11	12	13	12	11	10	0.89	0.41
Methotrexate + Sulfasalazine	5	5	3	3	3	5	0.76	0.98
Methotrexate + HCQS	5	7	9	8	4	5	0.28	0.23
Sulfasalazine+ HCQS	1	0	1	1	4	0	0.99	0.42
DMARD Mono								
HCQS	1	0	3	0	1	0	0.23	0.26
Sulfasalazine	0	0	0	0	2	0	-	-
Methotrexate	5	5	6	6	3	4	0.81	0.81
Total Use of DMARD (Single/Combo with or without Prednisolone)								
Methotrexate	47	50	50	48	34	49	0.00	0.60
Sulfasalazine	19	19	11	10	27	19	0.01	0.14
HCQS	23	19	23	20	27	17	0.27	0.88
Analgesic/NSAID Use								
Analgesic/NSAID	46(81)	40(75)	54(95)	39(75)	52(90)	43(81)	0.07	0.93
Equivalent paracetamol daily use ^ , gm, mean (SD)	1.85 (0.82)	1.37 -0.7	1.8 -0.77	1.41 -0.77	1.9 -0.85	1.46 -0.7	0.83	0.85

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Note: n: number of study participants; DMARD: disease modifying antirheumatic drug; Analgesic/NSAID[^]: Daily Analgesic use in varying and/or fixed dose >4 times a week (includes non-steroidal anti-inflammatory drugs/NSAID) ; Daily paracetamol use^{^^}: Combined use of paracetamol and Non-steroidal anti-inflammatory (NSAID) whereby NSAID use was converted into equivalent paracetamol dose by an equation decided a-priori by expert consensus (Each tablet of 50 Diclofenac/100 mg Nimesulide/60 mg Etorocoxib/300 mg etodolac were equated to 1000 mg paracetamol; *p1: baseline comparison of groups; *p2: completion comparison of groups: *: chi-square statistic (Yates correction), degrees of freedom 2, significant p <0.05; See text for details

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Table 5: Significant Pearson Moment correlation (r) between Diet nutrients and Energy Consumption at Baseline (B) and Study Completion (C) in patients with symptomatic RA randomized (n=172 patients) to a diet intervention drug trial; Data pertains to 155 patient completers.

Diet Variable	Positive 'r'	Negative 'r'
Potassium (B)	Sodium , Iron (C),	Protein(C),Zinc(C),Calcium (C),Thiamine (C) , Folic A(C)
Energy (B)	Protein (B)*, Zinc (B)*,Calcium (B), Thiamine(B)*, Iron (B), Folic acid (B) **, Sodium (B), Protein (C), Zinc(C), Calcium (C), Thiamine (C)*, Iron (C)*, Folic acid (C)*	
Protein (B)	Energy (B) *, zinc (B)*, calcium(B)*, thiamine (B)*, iron (B), folic acid (B) **, sodium (B), protein (C), zinc(C), calcium (C), thiamine (C)*, iron (C) *	Nil
Fat (B)	Nil	Nil
Calcium (B)	Energy (B), Protein (B)*, Zinc (B), Vitamin A (B), Thiamine (B) *, Iron (B)*, Folic acid (B) *, Sodium (B)*, Protein (C), Thiamine (C), Iron (C)	Nil
Thiamine (B)	Energy (B) *, Protein (B)*, Zinc (B)*,Calcium (B)*, Iron (B)*, Folic acid (B) *, Sodium (B), Protein (C)*, Zinc (C), Calcium (C), Thiamine (C)*, Iron (C) *, Folic acid (C)*	Nil
Vitamin C (B)	Nil	Calcium (C), Thiamine (C), Iron (C), Folic acid (C)
Iron (B)	Energy (B), Protein (B), Zinc (B), Calcium (B), Vitamin A (B), Thiamine (B) *, Folic acid (B), Sodium (B)	Nil
Folic Acid (B)	Energy (B)*, Protein (B)*, Zinc (B)*, Calcium (B), Vitamin A (B), Thiamine (B)*, Iron (B)*, Sodium (B), Protein (C)*, Zinc (C), Calcium (C), Thiamine (C)*, Iron (C)	Nil
Vitamin A (B)	Calcium (B)*, Iron (B), Folic acid (B)	Nil
Zinc (B)	Protein (B)*, Thiamine (B)*, Iron (B), Calcium (B), Folic acid (B) *, Sodium (B), Protein (C), Thiamine (C)*, Iron (C), folic acid (C)	Nil
Sodium(C)	Energy (C)*, Protein (C)*, Fat (C), Zinc(C)*, Calcium (C)*, Phosphate(C), Thiamine (C)*, *Iron (C)*, Folic acid (C)*, Vitamin A(C), Potassium (C)	Nil
Potassium (C)	Energy (C), Protein (C)*, Fat (C), Zinc (C)*, Calcium (C), Phosphate(C), Thiamine (C), Iron (C), Folic acid (C), Sodium (C)*	Vit C (B)

Note: n: number ; Diet variables: measured as daily quantity based on standard 'Food Composition Tables (India)'; Abbreviations and acronyms: see above methods; Significance at p<0.05 two tailed; * : p<0.01; See main text for further details

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Table 6: Variables used in Univariate and Logistic Regression Analysis: Definition and Classification of Variables (dummy binary codes- 1 and 2) and Dependent Variables- A Randomized Assessor Blind three Arm Controlled Diet Intervention Study of Symptomatic Rheumatoid Arthritis (RA) (n=172 patients) of 16 Weeks Duration.

Variables for Regression Analysis	Variable Label	Explanatory note / dummy code 1 (equivalent to Yes)
Potassium /K_Arm	K_Arm	Arm A or B, consumed potassium
K diet arm	K_5_diet arm	Arm A only
Age continuous (years)	Age	continuous data
Age stratified (years)	Age_40l	age less than 40 years
Duration (years)	R_5m	5 years or more
Tobacco	Tobacco	Yes
Menopause	Menopause	Yes
BMI stratified	BMI_25m	25Kg/m ² and more=overweight and obesity
Joint count pain tender (JCPT)	JCPT_1_7m	7 joints or more painful or tender baseline
Joint count swelling (JCSW)	JCSW_1_2m	2 joints or more swollen baseline
Health Assessment Questionnaire (HAQ)	HAQ_1_6m	6 (total 24) or more disability score baseline, more disability
Physician global assess	PGA_1_3m	3 or more category physician global assess disease severity baseline
Patient assessment disease (PAD)	PAD_!_3m	3 or more category patient global assess disease severity baseline
General Health Assess (GHA)	GHA_1_60l	60mm (VAS) or less score baseline to show more poor health
Early Morning Stiffness (EMS)	EMS_1_30m	30 min or more morning stiff baseline, more severe disease
Rheumatoid Arthritis Pain Score (RAPS)	RAPS_1_60m	60 or more baseline score for more pain
Disease activity score (DAS)	DAS_!_5.1m	DAS28 high on baseline > 5.1 more disease active
Short Form Health Score-physical 36 item (SF36P)	SF36P_1_40l	40 or less score baseline for more physical disability
Short Form Health Score-mental 36 item (SF36M)	SF36M_1_40l	40 or less score baseline for more mental disability
Erythrocyte Sediment Rate (ESR)	ESR_1_50m	50mm fall 1 st hour or more measure baseline for more disease severity
Serum Potassium (Sr K)	SrK_1_3.5l	3.5mEq/L or less assay baseline for lesser body potassium
Urine Potassium (K)	UrK_1_40m	40mg or more excretion baseline for more K loss
C-reactive protein (CRP)	CRP_1_12m	12mg/dl or more assay baseline for more disease severity
Rheumatoid Factor (RF) titre	RF_1_120m	120 IU/l or more assay baseline for more seropositive RA
Anti-cyclic citrullinated peptide (CCP) assay	CCP_1	>5 RU/l
Serum Cortisol (Sr Cort)	SrCort_1_7.5 less	Serum cortisol less than 7.5 mg baseline in more painful diseases
Serum Cortisol (Sr Cort)	SrCort_5_7.5 more	Serum cortisol more than 7.5 mg completion in less painful diseases

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Energy- daily diet consumption	Energy_1_2700m	2700 KCalories or more baseline Kcal consumption
Protein- daily diet consumption	Prot_1_80m	80gm or more protein baseline consumption
Zinc-daily diet consumption	Zn_1_15m	15mg or more zinc baseline consumption
Vitamin C (Vit) daily consumption	VitC_1_130m	130mg or more Vit C baseline consumption
Iron -daily diet consumption	Iron_1_30m	30mg or more Iron baseline consumption
Potassium (K)-daily diet consumption	K_1_2200l	2200 mg or less baseline consumption
Energy- daily diet consumption	Energy_5_2700m	2700 KCalories or more Kcal consumption on study completion
Protein- daily diet consumption	Prot_5_80m	80gm or more protein consumption on study completion
Zinc-daily diet consumption	Zn_5_15m	15mg or more zinc consumption on study completion
Calcium consumption diet	Cal_5_800m	800 mg or higher calcium consumption study completion
Vitamin C (Vit) daily consumption	VitC_5_130m	130mg or more Vit C consumption on study completion
Iron -daily diet consumption	iron_5_30m	30mg or more Iron consumption on study completion
Sodium (Na)-daily diet consumption	Na_5_4000m	4000mg or more consumption on study completion
K daily diet consumption - completion	K_5_5000m	5000mg or more consumption on study completion
K-daily diet consumption completion	K_5_4000	4000mg or more consumption on study completion
K daily diet consumption - completion	K_5_3000m	3000mg or more consumption RDA on study completion
Methotrexate (MTX) dose mg per week	MTX_1_16m	16mg or more weekly dose baseline for more disease activity
MTX use	MTX_1_yes	use of MTX at baseline
MTX+SZP (sulfasalazine) consumption	MTX_SZP_1_Yes	use of MTX SZP at baseline
Prednisolone (Pred) daily dose mg	Pred_1_6m	6mg or more daily dose of prednisolone at baseline, more active dis
Pred use	Pred_1_Yes	Prednisolone use at baseline
Non-steroidal inflammatory (NSAID) anti-use	NSAID_1_Yes	NSAID use at baseline
Combo use	Combo_1_Yes	Combination use of DMARD at baseline
Combo +Pred use	Combo_P_1_Yes	Combination DMARD plus prednisolone at baseline
MTX use on completion	MTX_5_Yes	MTX use on study completion
MTX dose use on completion	MTX_5_16m	MTX dose 16mg or more on study completion
Pred use on completion	Pred_5_Yes	Pred use on study completion
Pred dose on completion	Pred_5_6m	Pred dose 6mg or more daily on study completion
Combo Use	Combo_5-Yes	Combination DMARD on completion

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NSAID use on completion	NSAID_5_Yes	NSAID use on completion
Pain on completion	Pain_5_4l	Dependent Variable : pain less than 4 cm on VAS on study completion
Disease activity score using ESR less than 3.2	DAS28_5_low	Dependent Variable: DAS28 low disease or remission on study completion
Note: ; n: number; m:more;l:less; K: potassium; Combo: combination; MTX: methotrexate; Pred: prednisolone; SZP: sulfasalazine;		

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Table 7: Odds Ratio (Association) of Diet Variable and Nutrients with Dependent Variable using Univariate analysis (Z test): A Randomized Assessor Blind three Arm Controlled Diet Intervention Study of Symptomatic Rheumatoid Arthritis (RA) (n=172 patients) of 16 Weeks Duration.

Dependent Variable/ Diet related variable	Pain change MCID on study completion		Pain VAS on study completion less than 4 cm (VAS)		DAS28 score on study completion less than 3.2	
	OR	'Z' value [€]	OR	'Z' value [€]	OR	'Z' value [€]
K-arm	2.0134*	2.0069	1.5450	1.2749	1.2613	0.6474
K-diet-arm	0.9300	-0.2061	0.9285	-0.2152	1.1229	0.3203
SRK-1_3.5l	0.8467	-0.4363	0.6705	-1.0712	1.3344	0.7539
URK-1_40m	0.5481	-1.8163	0.4711*	-2.3234	1.3900	0.9675
Energy-1_2700m	0.4573*	-2.2719	0.6638	-1.2159	0.5944	-1.4589
Prot-1_80m	0.4805	-1.9691	0.7218	-0.8948	0.4993	-1.8144
Zn-1_15m	1.1794	0.4254	1.0340	0.0882	0.4639	-1.9244
VitC-1_130m	0.7054	-0.9959	0.5611	-1.6852	1.3828	0.8996
Iron-1_30m	1.5119	1.2419	1.2012	0.5628	0.6375	-1.3151
K-1_2200l	1.2631	0.6756	1.2777	0.7245	0.8308	-0.5212
Energy-5_2700m	1.3806	0.8907	0.9775	-0.0640	0.9246	-0.2103
Prot-5_80m	0.7950	-0.6114	1.0017	0.0047	0.5430	-1.5830
Zn-5_15m	1.8395	1.7396	2.0192*	2.0498	0.6301	-1.2815
Calcium__800m	1.6071	1.3102	1.5000	1.1443	0.7070	-0.9308
VitC-5_130m	0.8588	-0.3807	0.7428	-0.7599	1.0715	0.1681
Iron-5_30m	1.6898	1.5761	1.6532	1.5436	0.7166	-0.9732
Na-5_4000m	3.3526*	3.4002	2.5961*	2.7405	0.9427	-0.1611
K-5_5000m	3.8911*	3.5939	2.5909*	2.5737	0.9382	-0.1638
K-5_4000m PP	1.8417	1.7864	1.6561	1.5083	0.9448	-0.1614
K-5_3000m	1.8864	1.8889	1.5277	1.2891	0.9388	-0.1824

Note: n=number; OR: Odds Ratio and testing with population OR=1; €: Estimated after 'log' transformation;; *: Statistically Significant as 'Z' value is either greater than 1.96 or smaller than -1.96 and therefore included in 'Logistic Model'; several variables dummy (binary) coded as per investigator discretion and shown in Table 3; m:more; l:less; MCID: minimum clinically important difference (for pain VAS = 1 cm)

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Table 8: Logistic regression models (with stepwise forward) in a randomized controlled diet intervention study of symptomatic rheumatoid arthritis (RA) to determine predictors of low pain (4 cm or less on VAS) at study completion (16 weeks): Shows variables (predictors) with significant regression coefficients (Odds ratio) as output in 4 Models


Dependent Variable	Group Independent Variables and Method	R2	Predictor (Odds Ratio)
Pain VAS less than 40 cms on study completion	METHOD=ENTER:age_40less,RA>5 years, tobacco, menopause, BMI_25m,JCPT1_7m,JCSW1_2m,HAQ1_6m,PGA1_3m,P.A.D1_3m, GHA1_60less, EMS1_30m,RAPS1_60m,DAS1_5.1m , SF36P1_40l,SF36M1_40l,ESR1_50m, CRP1_12m,RF1_120m,MTX1_16m, MTX1_yes,MTX_SZP1_yes, PRED1_Yes, Pred1_6m,NSAID1_Yes, Combo1_Yes, ComboP1_Yes,MTX5_16more,MTX5 Yes, RED5_Yes,Pred5_6m, NSAID5_Yes, Combo5_yes,SrCort1, K_Arm ,K5_diet arm,SRK1_40ml,UrineK1_40m, ENERGY1_2700m,Prot1_80m, ZINC1_15m,VITC1_130m, IRON1_30m, K1_2200l,ENERGY5_2700M,Prot5_80m,ZINC5_15m,CALCIUM5_800M, VITC5_130m, IRON5_30m,Na5_4000 m, K5_5000m,K5_4000m, K5_3000m	60.7	Menopause (0.138), HAQ1_6m (0.225), GHA1_60less (0.129), DAS28_1_5more (12.51), RF1_120 more (4.65), MTX1_yes (108.09), Pred5_6more(0.055), K5diet arm (9.58), K5_5000m (20.893)
	METHOD=STEPWISE FORWARD; ALL VARIABLES AS ABOVE IN THE EQUATION; 6 steps to achieve optimum outcome	32.9	RA duration >5years (0.29), HAQ1_6more(0.346), MTX1_yes (16.096) , MTX_SZP1_yes (0.078) Pred5_6m (0.327), K5_5000m (2.876)
	METHOD=ENTER (Selected variables): age_40less,RA>5 years, menopause JCSW_1_2m P.A.D_1_3m, Pred_5_6m, K_Arm,ENERGY_1_2700more , Na_5_4000more, K_5_5000more	33	MTX1_yes (2.818), UrineK1_40 more, (0.42), RA duration > 5 year (0.341), HAQ1_6more (0.503), Menopause (0.51), GHA1_60less (0.376), ZINC5_15more (1.941)
	METHOD= STEPWISE FORWARD; ALL THE ABOVE SELECTED VARIABLES IN THE EQUATION; 4 steps.	25.3	RA duration>5years (0.295), HAQ1_6more(0.376), MTX1_yes (2.498), K5_5000more (3.145)

Supplement File 1_Additional Results

Note: All models achieved good fit; n: number; R2:percent of the variation explained by the predictors ,as per the method of Nagelkerke; See Table 6 for abbreviations





Supplement File 1_Additional Results

Fig 1: Diet Brochure Provided to Patients for Their Daily Meal Plans to Augment Potassium in the Diet: A Controlled Study of Diet and Food based K intervention in patients suffering from active symptomatic Rheumatoid Arthritis (RA) and Continuing Background Standard RA Medication


<p><i>RHEUMATOID ARTHRITIS AND POTASSIUM RICH FOOD</i></p>  <p><i>PATIENT DIET ADVICE BROCHURE</i></p> <p><i>Center for Rheumatic Disease (CRD), Pune</i></p> <p><i>Tel: 02026344099 02026355204</i></p>	<p>Diet plays important role in Rheumatoid Arthritis (RA) but there is limited scientific evidence. It is difficult for patients to have properly cooked food with adequate protein, vitamins and essential minerals. Also they should not put on excess body weight which can worsen symptoms of RA. Besides improving general health, diet may helps in reducing the severity and improving the control of arthritis. It is possible that symptom like pain can be managed to some extent to suitable dietary changes.</p> <p>A recent study from Iran in women with RA suggested that K+ supplement to diet reduced pain in joints. We recently carried out a study of patients suffering from RA in the Center for Rheumatic Diseases, Pune; to measure the dietary contents in patients of RA and found that the local diet was not sufficient in K. However this was an early limited study. We now need to understand in a large study to evaluate the role of K+ in diet in patients with RA. This study has been approved by independent Ethical Committee of the institute.</p> <p>We will be providing you advice regarding increase K+ in diet through eating K+ rich foods and some dietary supplement. Please follow the advice described below. Make sure you choose daily cereals or pulses or vegetable or fruits from the items listed below. You are welcome to eat different diet items on different days of week. For example: daily diet may be 3-4 chapatis or Bhakris or 2 katoris dal along with 1 katori vegetable and 1 fruit. You may like to divide the daily requirement between lunch and dinner.</p>
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Supplement File 1_Additional Results

Fig 1 (Continued)

<p>Diet advice:</p> <p>Cereal: In the form of Chapatti or Bhakri (4 chapati or bhakri in standard size in a day made of Ragi or Wheat flour or Jawar or Bajra)</p> <p>Ragi or wheat Jowar Bajra</p>  <p>Pulses: In the form of gravy (2 katori daily)</p> <p>Mung dal or Chawli or Tur dal</p>  <p>Vegetable: In the form of bhaji (2 katori daily)</p> <p>Shevga or Brinjal or Karela</p>  <p>Fruits: Take 1 Musambi and 1 Banana in the morning and evening</p>  <p>2 Musambi or 2 banana in a day</p>	<p><u>Do's</u></p> <ul style="list-style-type: none"> ➤ Drink lots of water, at least 2 liters in a day. ➤ You can consume common and popular vegetable like potato, onion garlic and home made chutney (pudina and green chilies). ➤ Methi seeds are also good source of K+ and you may take them as lado ➤ Methi seeds are also good source of K+ and you may take them as lado ➤ Jaggary may be eaten in any form of like puran poli. <p><u>Don't</u></p> <ul style="list-style-type: none"> ➤ Avoid oily and spicy food. You may use vegetable oil like ground nut or sunflower to cook food. ➤ Avoid tobacco use ➤ Avoid excess salt in diet. Don't add salt in cooked food. ➤ Avoid pickle and chutney or salted snacks like peanut and wafers. ➤ Don't fast or eat special food
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Supplement File 1_Additional Results




TEST REPORT

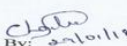
Analytical Report Number: QL/MI/18/0005		Report Date: 29.01.2018	
Manufacturer's/Customer Name: M/s. ARTHRITIS RESEARCH AND CARE FOUNDATION CENTER FOR RHEUMATIC DISEASES		Manufacturer's Licence No.: NA	
Issued to: M/s. ARTHRITIS RESEARCH AND CARE FOUNDATION CENTER FOR RHEUMATIC DISEASES No.11, Hemes Elegance, 1988, Convent Street, Camp, Pune: 411001, INDIA.		Customer Reference: NA	
		Date of Receipt: 12.07.2017	
		Date of Completion of Test: 24.01.2018	
Sample Nature/ Name: CRD PUNE K-JOINT 30°C/75%RH, 6M		Batch Number: NA	
		Batch size: NA	
Sample Condition: Received in a container.		Manufacture Date: NA	
		Expiry Date: NA	

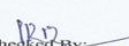
S. No	Test Parameters	Specification Limit	Results
	Description	Brown coloured powder	
I) Nutritional Labelling, Each 100g Contains			
1	Calories, g	Record the value	380.42
2	Total Protein, g	Record the value	17.8
3	Total Carbohydrate, g	Record the value	77.56
4	Total Fat, g	Record the value	0.49
5	Vitamin A	Record the value	Not detected
6	Vitamin D	Record the value	Not detected
7	Vitamin E	Record the value	Not detected
8	Vitamin B1	Record the value	Not detected
9	Vitamin B2	Record the value	Not detected
10	Vitamin B3	Record the value	Not detected
11	Vitamin B4	Record the value	Not detected
12	Vitamin C	Record the value	Not detected
13	Calcium as Ca, g	Record the value	0.78


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14	Potassium as K, g	Record the value	2.36
15	Zinc as Zn, g	Record the value	3.6
16	Selenium as Se, g	Record the value	Below detection limit
17	Magnesium as Mg, g	Record the value	0.45
18	Iron as Fe, mg/kg	Record the value	45.42
19	Sodium as Na, in %	Record the value	2.36
II) Microbial Analysis			
1	Total Aerobic Microbial count/g	Record the value	556 cfu
2	Staphylococcus aureus/g	Record the value	Less than 10 cfu
3	Escherichia coli/g	Record the value	Absent
4	Yeast and Mould count/g	Record the value	Less than 10cfu
5	Salmonella/25g	Record the value	Absent
6	Pseudomonas Aeruginosa/g	Record the value	Absent

Prepared By:  29/01/18

Checked By:  29/01/18

Authorised signatory:  29/01/18