Effect of Personalized Diet and Exercise Recommendations in Early Inflammatory Arthritis: A Randomized Trial

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Background

- The diagnosis of rheumatoid arthritis (RA) is a life-altering event affecting a patient's sense of self, well-being and control (1).
- Non-pharmacological interventions such as physical activity and diet modification have shown to be important and have a positive impact on disease activity, prognosis and cardiovascular disease (2, 3, 4).
- At time of diagnosis patients may be highly motivated to improve their overall health, and a lifestyle intervention at this time might be more readily accepted (5).
- Motivational interviewing has proven effective in improving self-efficacy, patient activation, lifestyle changes, and perceived health status in chronic illnesses (6).
- Motivational interviewing may be beneficial in RA management, but few formal studies have been reported (6).

Objective

This was a six-month feasibility trial, where we examined the effect of a brief individualized counseling intervention on physical activity and dietary intake, compared to standard of care.

Methods

Subjects

- Thirty patients were recruited from the Early Inflammatory Arthritis clinics held in the Division of Rheumatology at the University of Calgary from May 2012 to January 2015.
- *Inclusion criteria:* New diagnosis of RA (ACR 2010) and on a DMARD.
- *Exclusion criteria:* Uncontrolled hyperlipidemia, uncontrolled hypertension, uncontrolled diabetes or pregnancy

Intervention:

- Standard care: review with physiotherapist, provision of Canada's Food Guide, Nutrition in Arthritis handbook and the Arthritis Education Program (group education in RA), medication information and exercise recommendations.
- Intervention group: Standard care plus individualized nutrition and exercise counseling session with a dietetic intern and physiotherapist at enrollment and three months that was tailored to their age and gender. Patients received a pedometer to track steps.

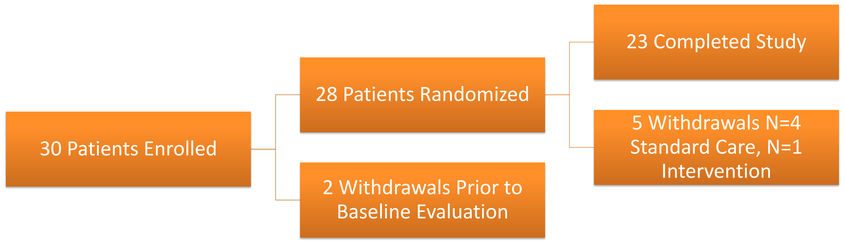
Outcome measures:

- *Anthropometric Measures and Biochemical Testing:* height, weight, waist/hip circumference, BP, cholesterol profile, and random glucose.
- *Nutritional intake:* National Cancer Institute's Food Frequency Questionnaire (7).
- *Physical activity and fitness:* pedometer steps per week, Timed Up and Go Test, Timed Stand Test, One Repetition Maximum for lateral arm raise, six minute walk test and Sit and Reach test.
- *Treatment and disease activity:* Baseline and 6 month evaluations, subjects' tender and swollen joint counts, visual analogue scale for global well-being, function using the Health Assessment Questionnaire (HAQ), DAS28 score, and CRP/ESR.

Study was approved by the University of Calgary Conjoint Health Research Ethics Board.

Results

Figure 1:Patient randomization and follow-up



Baseline Characteristics

- Pre-existing cardiovascular risk factors were rare.
- Two patients in the intervention group and one in the standard care group had controlled hypertension, one patient in the standard care group had dyslipidemia.
- There were no patients with diabetes in either study group.

Table 1. Baseline Characteristics of Standard Care and Intervention Groups

Outcome	Standard Care (n= 14)	Intervention (n= 14)	P value
Age (years); mean (SD)	49 (14)	45 (10)	0.3
Female; n (%)	10 (71)	13 (93)	0.3
Days since Diagnosis; mean (SD)	21 (13)	23 (30)	0.8
Seropositive; n (%)	12 (86)	12 (86)	0.7
Current Smoker, n (%)	3 (21)	1 (7)	0.6
LDL (mmol/L); mean (SD)	2.74 (1.02)	2.33 (1.20)	0.3
Body Mass Index; mean (SD)	27.2 (7.3)	25.4 (4.3)	0.4
Systolic BP; mean (SD)	128 (13)	126 (13)	0.7
Diastolic BP; mean (SD)	80 (10)	77 (11)	0.4
Waist Hip Ratio; mean (SD)	0.87 (0.07)	0.83 (0.06)	0.1
No Comorbid Conditions, n (%)	7 (50)	11 (79)	0.3
Swollen Joint Count (28 joints); mean (SD)	12.4 (8.4)	3.6 (4.5)	0.002
Tender Joint Count (28 joints); mean (SD)	14.1 (8.0)	4.4 (4.9)	0.001
Patient Global (0-100 VAS); mean (SD)	45.7 (27.1)	35.7 (17.0)	0.2
ESR (mm/hour); mean (SD)	21.6 (18.1)	12.8 (9.6)	0.1
CRP (mg/L); mean (SD)	18.6 (30.4)	3.1 (5.4)	0.08
DAS28; mean (SD)	5.5 (1.4)	3.5 (1.1)	0.001
HAQ; mean (SD)	1.0 (0.9)	0.6 (0.4)	0.09

Disease Activity and Treatment:

- All 14 patients in the control group and 12/14 patients in the intervention group were taking methotrexate. The other two patients in the intervention group were on hydroxychloroquine and hydroxychloroquine with sulphasalazine respectively.
- Over the course of their study involvement both groups demonstrated improvement in their disease activity with similar improvements in their DAS28 scores and joint counts (standard care mean change -2.63 (SD 2.31), intervention -1.31 (1.52) p=0.1)
- At the end of six months, the patients in both study groups remained on the medication that they had been prescribed at the beginning of the study with some patients requiring adjustment to the dose of their therapy.

Table 2: Change in Anthropometric and Biochemical Measures Over 6 Months

Mean (SD)	Standard Care (n= 10)	Intervention (n= 13)	P Value
Body Mass Index ; mean (SD)	-0.30 (0.90)	-0.23 (0.73)	NS
Waist to hip ratio; mean (SD)	-0.03 (0.05)	-0.01 (0.07)	NS
LDL (mmol/L); mean (SD)	-0.09 (1.11)	-0.23 (1.53)	NS
Systolic BP; mean (SD)	-4.4 (18.2)	-7.1 (7.8)	NS
Diastolic BP; mean (SD)	-3.3 (10.4)	-0.69 (8.8)	NS

Nutritional Intake:

- At baseline both groups had inadequate intake of fibre, folate and calcium.
- At follow-up, there were greater increases in vitamin C, iron, fibre, vitamin A and folate intake in the intervention group, but these intake increases were not statistically significant.
- Energy intake decreased in both groups (standard care -360kcal/day, intervention group -210 kcal/day p NS). The veracity of these reported changes in energy intake were not reflected in the small decreases in weight which were found in both groups at the end of the study.

Table 3: Physical Fitness In Standard Care and Intervention Groups

	Standard Care Group		Intervention Group		
	Baseline	Change at End of Study	Baseline	Change at End of Study	Change Between Groups
Pedometer Steps (One Week)	41894 (25708)	6696 (17032)	43430 (22339)	9583 (11959)	NS
Timed up and go test (seconds)	8.3 (2.2)	-0.42 (0.99)	7.6 (1.5)	-0.52 (1.21)	NS
Timed Stand Test (seconds)	26.8 (8.7)	-4.3 (4.2)	25.3 (8.5)	-3.3 (4.3)	NS
Sit and Reach test (cm)	9.5 (4.0)	1.4 (3.6)	11.8 (3.6)	0.1 (2.0)	NS
One Repetition Maximum of the lateral arm raise (lbs)	9.4 (3.3)	-0.73 (4.94)	10.8 (1.9)	0.38 (2.36)	NS
6 Minute Walk Test (meters)	473.4 (71.3)	-6.8 (51.4)	501.9 (97.4)	-45.7 (64.7)	NS

Discussion

- While the intervention group did show some improvement in terms of nutritional intake, statistical significance was not demonstrated.
- The number of pedometer steps taken by participants in both groups and led to a non-significant increase in functional fitness, as demonstrated by the 6 minute walk test, in the intervention group. LDL also improved but not significantly.
- Unfortunately, despite randomization, our participant groups had significant baseline differences.
- The small sample size and high drop-out rate (23.3%) affected the ability to assess for differences in outcomes between the two groups.
- Our results further support previous research that diet and exercise interventions can be quite difficult to implement and high drop-out rates are common (8, 9, 10).

Conclusion

- Our trial of an individualized dietary intervention and detailed exercise prescription in early inflammatory arthritis demonstrated some ability to improve activity levels and dietary intakes in the short-term.
- Addressing individual behavioral factors in a population with a new chronic disease diagnosis will require a different approach.

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