Mental health in Scleroderma during COVID-19:
The SPIN COVID-19 Cohort and Home-isolation Activities Together (SPIN-CHAT) Trial

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Disclosures

Conflicts of Interest: None to declare.

The SPIN Story

People with rare diseases face unique challenges.
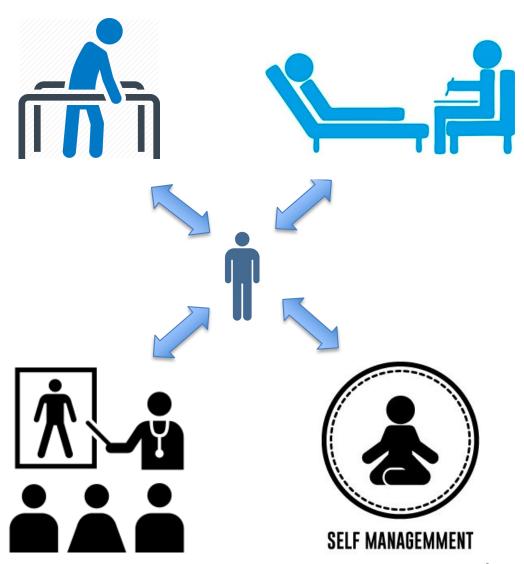
They may have difficulty getting an accurate diagnosis. Once diagnosed, they often face a lack of effective treatments and support programs that are often available in more common diseases.

The SPIN Story

In common diseases, medical care often includes:

- Patient education
- Self-management tools
- Physical rehabilitation
- Psychological support

SELF MANAGEMMENT

SPIN's Mission

To develop, test, and disseminate free-of-charge accessible educational, self-management, psychological, rehabilitation, and support tools to people around the world who live with scleroderma.

SPIN's approach includes:

- Robust patient organization partnerships

- An international network of clinical research centers

- A cohort-based research infrastructure to test patient programs

- Online and videoconference programs to maximize accessibility

SPIN Patient Organization Partners

Rheumatologists and Other Health Care Providers from 50+ Centers in 9 Countries:

Christopher Denton, MD, PhD
University College London

Dan Furst, MD
Geffen School of Medicine
U of California

John Varga, MD
University of Michigan

Dominique Farge-Bancel, MD
Hôpital St-Louis
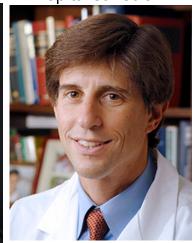
Maureen Mayes, MD
University of Texas

Marie Hudson, MD
McGill University

Janet Pope, MD
Western University

Laura Hummers, MD
Johns Hopkins

Robert Spiera, MD
Weill Cornell
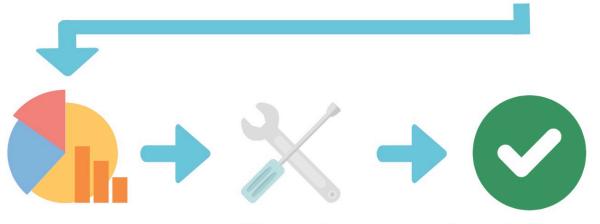
Luc Mouthon, MD, PhD
Hôpital Cochin

The SPIN Cohort

*1,700+ active patients   *50 clinical recruiting sites
*7 countries   *3 languages

People with scleroderma register for the cohort with a participating rheumatologist or scleroderma healthcare provider.

Every 3 months, cohort participants receive an email letting them know that it's time to complete an assessment.

Cohort participants log into SPIN's system on their computer, tablet, or smartphone, and answer questions about scleroderma-related symptoms and problems.

This data helps medical experts understand the disease better, including which problems are most burdensome to people with scleroderma.

SPIN uses this data to develop scleroderma-specific tools to help people manage and cope with the disease.

Some participants may be eligible and invited to try SPIN tools. Once tested, the tools are released to the public.
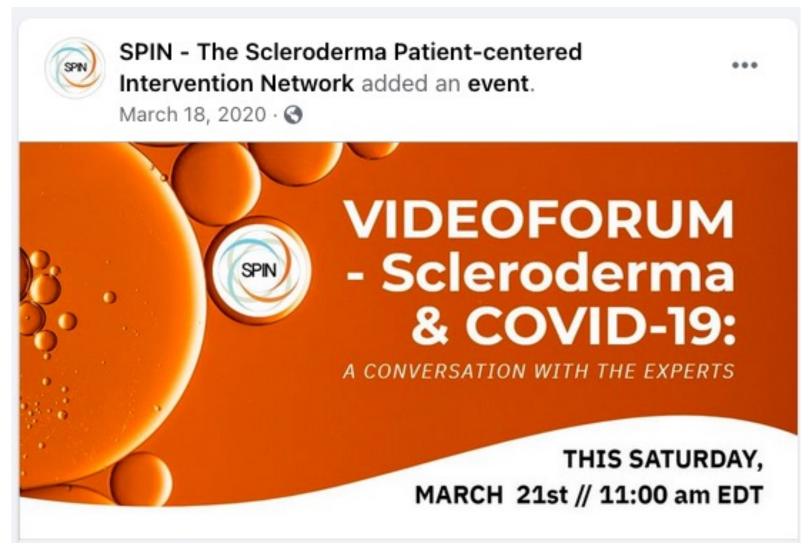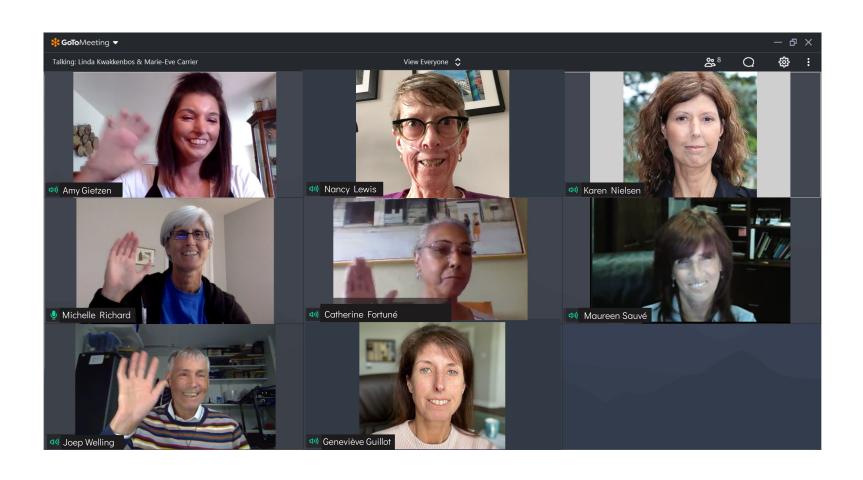
COVID-19

SPIN COVID-19 "Videoforum": March 21

SPIN and COVID-19: Patient Advisory Team

COVID-19 Fears Survey: March 26-29 (N = 121)

Contents lists available at ScienceDirect

Journal of Psychosomatic Research

journal homepage: www.elsevier.com/locate/jpsychores

Validation of the COVID-19 Fears Questionnaires for Chronic Medical Conditions: A Scleroderma Patient-centered Intervention Network COVID-19 Cohort study

Yin Wu[a,b], Linda Kwakkenbos[c], Richard S. Henry[a,b], Lydia Tao[a], Sami Harb[a,b], Angelica Bourgeault[a], Marie-Eve Carrier[a], Brooke Levis[d], Ying Sun[a], Parash Mani Bhandari[a,e], Andrea Carboni-Jiménez[a,b], Maria Gagarine[a,e], Chen He[a], Ankur Krishnan[a], Zelalem F. Negeri[a,e], Dipika Neupane[a,e], Luc Mouthon[g,h], Susan J. Bartlett[i,j], Andrea Benedetti[e,f,i], Brett D. Thombs[a,b,e,k,l,m,*], on behalf of the Scleroderma Patient-centered Intervention Network (SPIN) COVID-19 Investigators (Nicole Culos-Reed[a], Ghassan El-Baalbaki[b], Shannon Hebblethwaite[c], Scott Patten[a], John Varga[d], Laura Bustamante[c], Delaney Duchek[a], Kelsey Ellis[a], Danielle Rice[e]), SPIN COVID-19 Patient Advisory Team (Laura Dyas[f], Catherine Fortuné[g], Amy Gietzen[h], Geneviève Guillot[i], Nancy Lewis[j], Karen Nielsen[k], Michelle Richard[l], Maureen Sauvé[m], Joep Welling[n])

The SPIN-COVID-19 Cohort

- **New SPIN-COVID-19 Cohort**:

  - ❖ Evaluate the impact of the COVID-19 mental health in people living with scleroderma.
  - ❖ Gain a greater understanding of the experiences of people living with scleroderma during the pandemic.
  - ❖ Recruitment from SPIN Cohort and social media
  - ❖ Assessments initially every 2 weeks then every month beginning Fall 2020
  - ❖ Identify and recruit eligible participants to take part in the SPIN-CHAT Program trial.

The SPIN COVID-19 Cohort:
Enrolment April 9 to April 27, 2020

- April 9 to April 27, N = 800

The SPIN COVID-19 Cohort: Enrolment April 9 to April 27, 2020

Variable	SPIN-COVID Baseline Value N = 787
Demographic	
Age in years, mean (SD)	56 (13)
Female sex, %	90%
Education in years, mean (SD)	16 (4)
Married or living as married, %	69%
Race/ethnicity, %	
White	83%
Black	7%
Other	10%
Country, %	
Canada	25%
United States	32%
France	26%
United Kingdom	9%
Australia	6%
Other	4%
Disease characteristics	
Time since diagnosis in years, mean (SD)	12 (8)
Diffuse disease subtype, %	42%

The SPIN COVID-19 Fears Questionnaire (N = 787): Not at all to Extremely (1 to 5)

Item	% Very or Extremely Afraid
I will be infected and experience more severe complications because of my condition	52%
I will need to be isolated for longer than others because of my condition	46%
I will be infected and healthcare professionals will not be familiar with the needs of a person with my condition	43%
People close to me (e.g., family, close friends) will be infected and become ill	38%
I will become infected when I have to leave the house to get supplies or when supplies are brought to me	33%
I will be infected with the virus	33%
I will be infected and will not receive the medical treatment I need	29%
I will not be able to access health care that I need for my condition	27%
I will not be able to access medications I need for my condition due to shortages	20%
I will not be able to obtain basic supplies (e.g., food, other household necessities)	10%

Mental Health in COVID-19: Compared to pre-COVID-19

Changes in mental health symptoms from pre-COVID-19 to COVID-19 among participants with systemic sclerosis from four countries: A Scleroderma Patient-centered Intervention Network (SPIN) Cohort study

- International (Canada, USA, UK, France) systemic sclerosis cohort linked to COVID-19 cohort.

- April 9 to 27, 2020 compared to June - December 2019

- N = 435 included in comparison

- PHQ-9 (depression symptoms); PROMIS Anxiety 4a v1.0 (anxiety symptoms)

Mental Health in COVID-19:
Compared to pre-COVID-19 (N = 435)

Factors Associated with Change in Anxiety Symptoms (N = 435)

Table 4
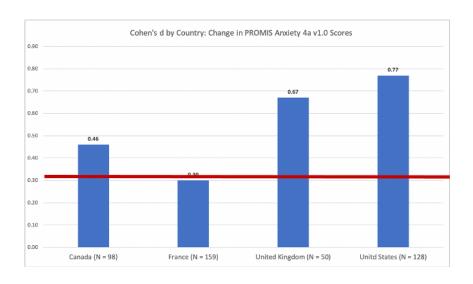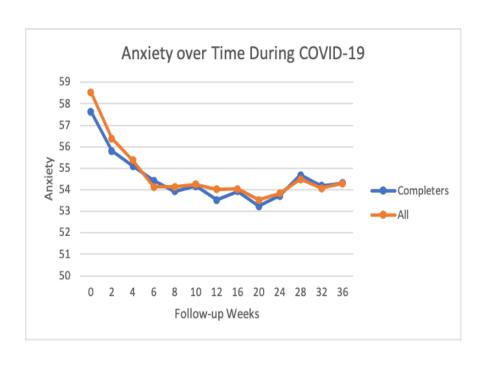
Multivariable Analysis of Factors Associated with Change in Continuous Anxiety Symptom Scores Pre-COVID-19 to COVID-19.
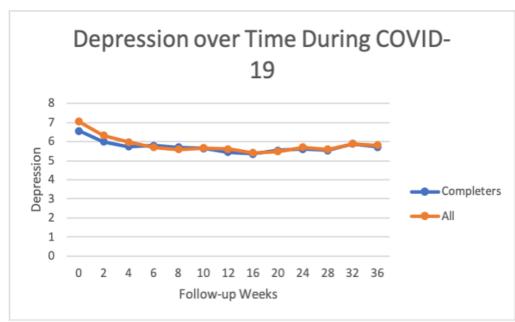
Variable	Unadjusted Regression Coefficient[a] (95% Confidence Interval)	Adjusted Regression Coefficient[a] (95% Confidence Interval)
Baseline Anxiety Symptoms		
PROMIS Anxiety pre-COVID (continuous)	−0.50 (−0.56 to −0.44)	−0.56 (−0.64 to −0.48)
Sociodemographic		
Age in years (continuous)	0.02 (−0.05 to 0.08)	−0.07 (−0.13 to −0.01)
Male sex (reference = female)	−0.58 (−3.20 to 2.03)	−1.52 (−3.75 to 2.33)
Education in years (continuous)	0.09 (−0.14 to 0.31)	−0.03 (−0.22 to 0.16)
Living alone (reference = living with others)	1.18 (−0.98 to 3.35)	0.93 (−0.81 to 2.68)
"Other" Race or ethnicity (reference = White)	−1.15 (−3.37 to 1.07)	0.47 (−1.40 to 2.33)
Working part- or full-time (reference = not working)	0.50 (−1.17 to 2.18)	−1.09 (−2.54 to 0.36)
Country (reference = France)		
Canada	1.22 (−0.98 to 3.43)	1.93 (0.08 to 3.80)
United Kingdom	3.05 (0.27 to 5.84)	3.27 (0.91 to 5.64)
United States	3.81 (1.78 to 5.85)	2.47 (0.69 to 4.24)
Medical characteristics		
Body mass index (reference = underweight or normal)		
Overweight	0.96 (−1.03 to 2.95)	−0.72 (−2.39 to 0.94)
Obese	0.81 (−1.52 to 3.15)	1.09 (−0.90 to 3.08)
Time since diagnosis of SSc (continuous)	0.11 (0.01 to 0.22)	0.03 (−0.07 to 0.13)
Diffuse disease subtype (reference = limited or sine)	−0.65 (−2.36 to 1.06)	−0.53 (−2.03 to 0.97)
Presence of interstitial lung disease (reference = no)	0.04 (−1.72 to 1.80)	0.49 (−1.07 to 2.06)
Presence of any overlap syndrome (reference = no)	−0.18 (−2.17 to 1.80)	0.23 (−1.45 to 1.91)
Immunosuppressant drug use (reference = no)	−0.34 (−2.01 to 1.33)	0.20 (−1.35 to 1.75)
Pre-COVID-19 use of mental health services (reference = no)	−4.18 (−6.19 to −2.18)	−0.18 (−1.93 to 1.58)
Interference from breathing problems (continuous)	−0.54 (−0.83 to −0.26)	−0.00 (−0.29 to 0.29)
PROMIS Physical Function pre-COVID (continuous)	0.19 (0.10 to 0.29)	0.02 (−0.08 to 0.12)
COVID-19 variables:		
Adequacy of financial resources = continuous	0.23 (0.06 to 0.40)	−0.24 (−0.40 to −0.08)

[a] Results based on imputed datasets. Based on assessment using via restricted cubic splines, there was no appreciable non-linearity.

Mental Health Symptoms Across the Pandemic (N = 800 to app. 400)

The COVID-19 Cohort and Home-isolation Activities Together (SPIN-CHAT) Trial

Brett D. Thombs, Linda Kwakkenbos, Brooke Levis, Angelica Bourgeault, Richard S. Henry, Alexander W. Levis, Sami Harb, Lydia Tao, Marie-Eve Carrier, Laura Bustamante, Delaney Duchek, Laura Dyas, Ghassan El-Baalbaki, Kelsey Ellis, Danielle B. Rice, Amanda Wurz, Julia Nordlund, Maria Gagarine, Kimberly A. Turner, Nora Østbø, Nicole Culos-Reed, Shannon Hebblethwaite, Scott Patten, Susan J. Bartlett, John Varga, Luc Mouthon, Sarah Markham, Michael S. Martin, Andrea Benedetti, and the SPIN-CHAT Patient Advisory Team and Program Facilitators, on behalf of the Scleroderma Patient-centered Intervention Network Investigators

Lancet Rheumatology, in press

Mental Health in COVID-19: A Multi-faceted Problem

- **Anxiety,** Fear, Worry
  - Infection, complications, death
  - Health care access
  - Loved ones
- Loneliness, Long-term isolation, Disconnection, Boredom
- Information and Disinformation, Misinformation

Mental Health in COVID-19: A Multi-faceted Strategy

- Information management
- Interpersonal connection and social support
- Activity engagement
- Physical activity
- Mental health strategies

The SPIN-CHAT Program

Objective: to improve symptoms of anxiety and other mental health consequences among individuals with scleroderma at risk of poor mental health

- 3 x 60-90 minute sessions per week (4 weeks)
  - Engagement – recreational therapist
  - Coping strategies – professional educator
  - Social support – trained peer facilitator (SPIN-SSLED)

- Sessions done over videoconference (GoToMeeting) in English or French
  - Program overview and group introductions (session 1)
  - Information management and social connection (session 2)
  - Worry management (sessions 3, 7, 11)
    - Function of worry, difference between helpful and unhelpful worry
    - Worry postponement for "solvable problems" and dedicated times
  - Relaxation techniques (sessions 4, 8)
  - Adapted home exercise (sessions 5, 9 12)
  - Home activity engagement (sessions 6, 10)

The SPIN-CHAT Trial

- ❖ Design: Pragmatic, two-arm parallel partially nested RCT (PN-RCT) with 1:1 randomization to intervention or waitlist control
- ❖ Eligibility
  - ❖ at least mild anxiety symptoms (PROMIS Anxiety 4a v1.0 T-score ≥55)
  - ❖ No current psychological services
  - ❖ No positive COVID-19 test
- ❖ Outcomes assessed post-intervention and 6 weeks post-intervention
- ❖ Primary outcome = anxiety symptoms (PROMIS Anxiety 4a v1.0)
- ❖ Secondary outcomes
  - ❖ Depressive symptoms (PHQ-9)
  - ❖ COVID-19 fear (COVID-19 Fears Questionnaire)
  - ❖ Loneliness (UCLA Loneliness Scale – 6)
  - ❖ Boredom (Multi-dimensional Boredom Scale – 8)
  - ❖ Physical activity level (International Physical Activity Questionnaire – Elderly)
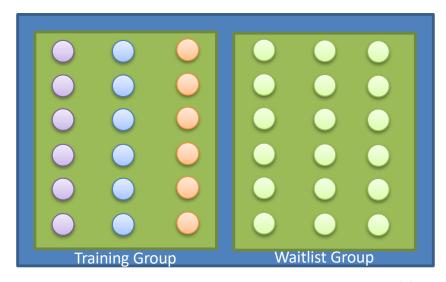- ❖ Intent-to-treat analysis with linear mixed-effects model and multiple imputation by chained equations

The SPIN-SSLED Program: Next Steps

Randomization – in 3 waves/weeks

- A third party randomization service will select from the list of participants available for the session
  - 6-10 participants for the training group
  - 6-10 participants for the waitlist group
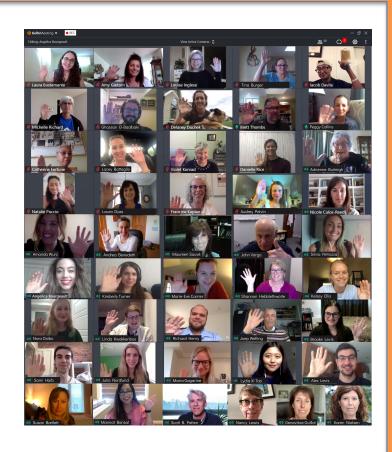- This process is repeated 2 other times for the other 2 groups

○ Group 1 of the wave   ○ Group 2 of the wave

○ Group 3 of the wave   ○ Waitlist group

Training Group   Waitlist Group

The SPIN-CHAT Trial

- ❖ 172 participants from 12 countries
    - ❖ 11 intervention groups in 3 waves
    - ❖ 6-10 participants per grou
- ❖ Team
    - ❖ 14 trained peer support group leaders
    - ❖ 6 educators
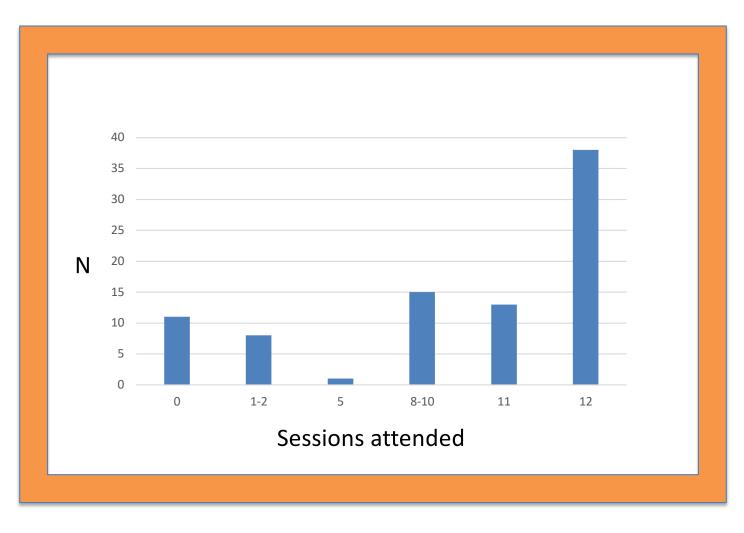   - ❖ SPIN Team
    - ❖ Content experts, methodologists, biostatisticians

The SPIN-CHAT Program: Participants

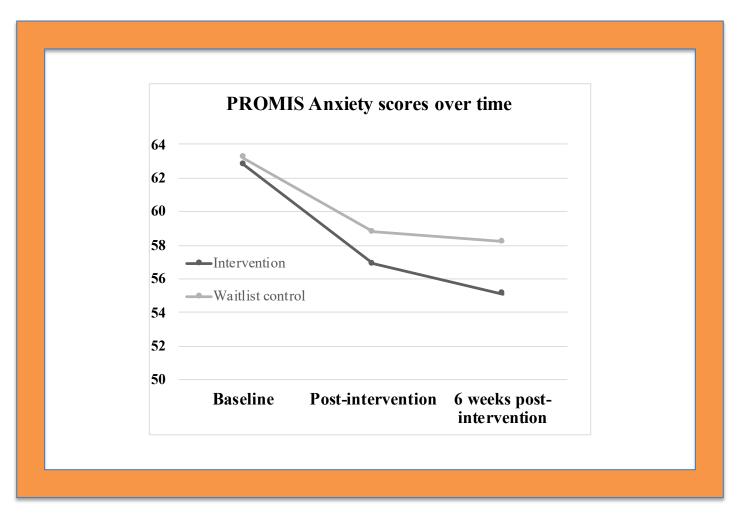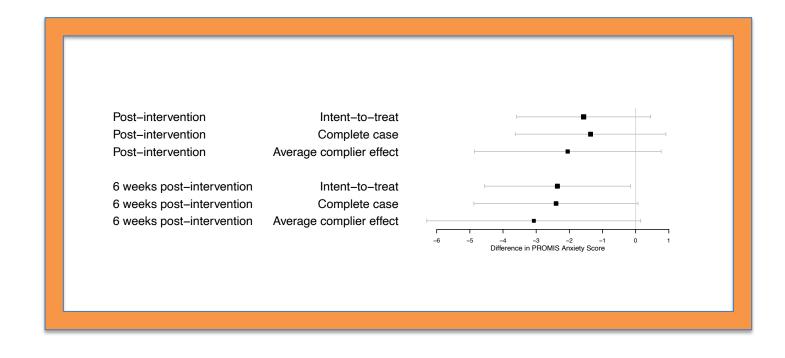|	SPIN-CHAT N = 86	Waitlist control N = 86	Eligible participants not in trial N = 388
Demographic			
Age in years, mean (SD)	56 (12)	54 (11)	54 (13)
Female, N (%)	81 (94)	81 (94)	347 (90)
Education in years, mean (SD)	15 (3)	16 (3)	16 (3)
Married or living as married, N (%)	53 (63)	51 (60)	271 (70)
Living alone, N (%)	13 (15)	21 (24)	59 (16)
Working parttime or fulltime, N (%)	37 (43)	29 (34)	155 (40)
White Race/ethnicity, N (%)	73 (85)	63 (73)	320 (84)
Country, N (%)			
Canada	27 (31)	23 (27)	103 (27)
United States	27 (31)	34 (40)	123 (32)
France	14 (16)	14 (16)	92 (24)
United Kingdom	7 (8)	5 (6)	38 (10)
Australia	6 (7)	5 (6)	17 (4)
Other	5 (6)	5 (6)	14 (4)
Disease characteristics			
Time since diagnosis in years, mean (SD)	11.1 (8)	11.4 (8)	11.3 (8)
Diffuse disease subtype, N (%)[j]	36 (46)	37 (47)	156 (41)

The SPIN-CHAT: Sessions Attended

The SPIN-CHAT:
Primary Outcome (Anxiety Symptoms)

PROMIS Anxiety scores over time

- Intervention
- Waitlist control

X-axis: Baseline, Post-intervention, 6 weeks post-intervention
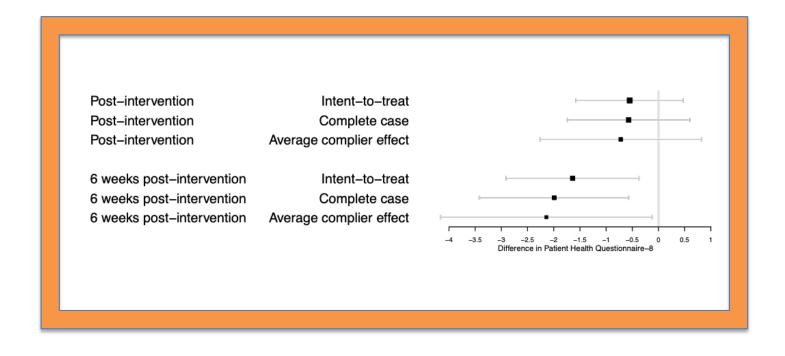Y-axis: 50, 52, 54, 56, 58, 60, 62, 64

The SPIN-CHAT:
Primary Outcome (Anxiety Symptoms)
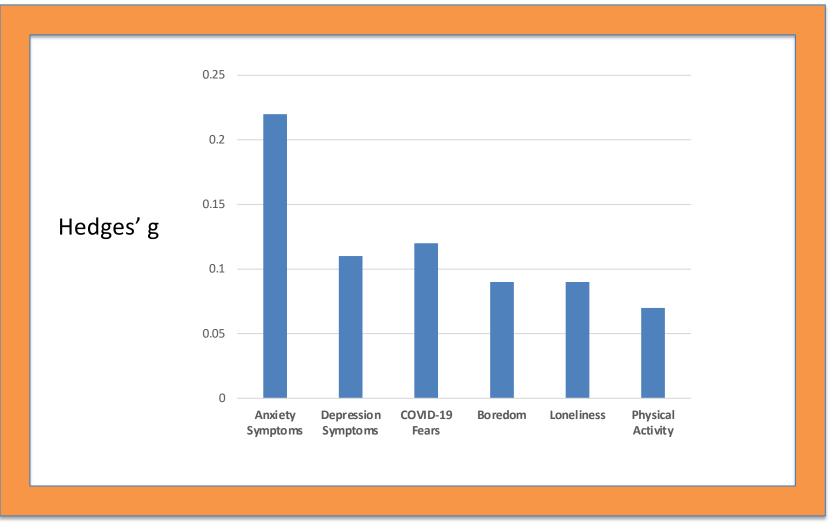
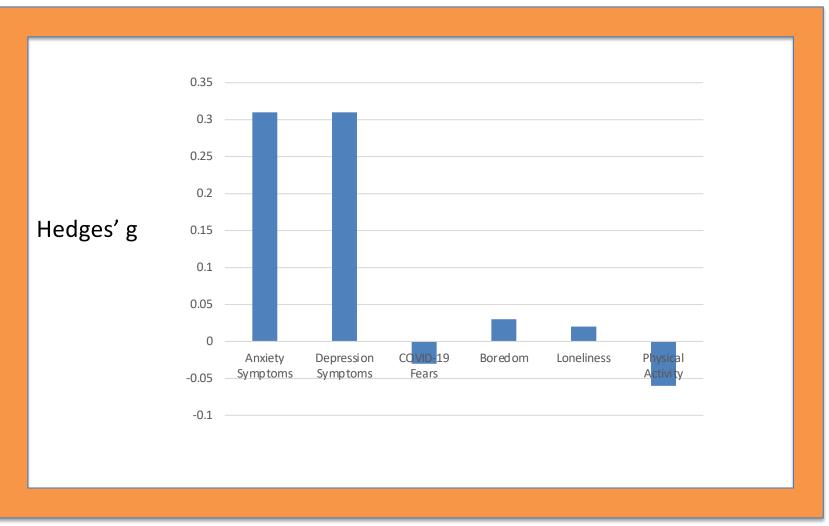# The SPIN-CHAT:
Secondary Outcome (Depressive Symptoms)

The SPIN-CHAT:
Post-intervention Outcomes

The SPIN-CHAT:
6 weeks Post-intervention Outcomes

Hedges' g

SPIN-CHAT: Conclusions

- The intervention did not significantly improve mental health outcomes post-intervention.

- However, anxiety and depression symptoms were significantly lower 6 weeks later, potentially capturing the time it took for new skills and social support between intervention participants to affect mental health.

- Multi-faceted interventions like SPIN-CHAT have potential to address mental health needs in vulnerable groups during COVID-19, yet uncertainty remains about effectiveness.

SPIN-COVID-19 Team

Linda Kwakkenbos, Brooke Levis, Angelica Bourgeault, Richard Henry, Alexander Levis, Sami Harb, Lydia Tao, Marie-Eve Carrier, Laura Bustamante, Delaney Duchek, Laura Dyas, Ghassan El-Baalbaki, Kelsey Ellis, Danielle Rice, Amanda Wurz, Julia Nordlund, Maria Gagarine, Kimberly Turner, Nora Østbø, Nicole Culos-Reed, Shannon Hebblethwaite, Scott Patten, Susan Bartlett, John Varga, Luc Mouthon, Sarah Markham, Michael Martin, Andrea Benedetti

Lacey Battaglio, Tina Burger, Adrienne Burleigh, Peggy Collins, Jacob Davila, Catherine Fortuné, Amy Gietzen, Geneviève Guillot, Louise Inglese, Franny Kaplan, Violet Konrad, Nancy Lewis, Karen Nielsen, Silvia Petrozza, Audrey Potvin, Natalie Puccio, Michelle Richard, Maureen Sauvé, Joep Welling

On behalf of the SPIN Investigators

Thank you to SPIN's French Sites

France		
Hôpital Cochin	Paris	Ile de France
Centre Hospitalier Universitaire de Rouen	Rouen	Normandie
Hôpital St-Antoine	Paris	Ile de France
Nouvel Hôpital Civil	Strasbourg	Grand Est
Hôpital St-Louis	Paris	Ile de France
Hôpital Claude Huriez	Lille	Hauts de France
Hôpital Nord	Marseille	Provence-Alpes-Côte d'Azur
UNEOS - Groupe hospitalier associatif	Metz	Grand Est
Centre Hospitalier Lyon Sud	Lyon	Auvergne-Rhône-Alpes
Centre Hospitalier Universitaire Dijon	Dijon	Bourgogne-Franche-Comté
Centre Hospitalier Universitaire de Nantes – Hôtel Dieu	Nantes	Pays de la Loire
Centre Hospitalier Gabriel Montpied	Clermont-Ferrand	Auvergne-Rhône-Alpes

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